

Guinea Pig Zero

#8

\$5.00

What's in this Issue:

Two lawsuits
filed against
University of
Pennsylvania
scientists

Feature articles:

Paul Gelsinger
on "Jesse's Intent"

Nancy King
on the Ethics of
Patient-subjects

Research Unit Report Cards
Guinea Pigs in Weird History

Poetry, Fiction,
and plenty more!



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Guinea Pig Zero

A Journal for Human Research Subjects

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Web site (which has a sampling of GPZ articles, not the whole contents): <http://hop.to/guineapigzero>

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Advertising Policy: This is a partisan journal, advocating the rights of human research subjects. Ads must not compromise the mission. Write or email GPZ for further information. Please note that there has never been a single ad in this journal throughout its existence.

Thanks! I send my sincere gratitude to everyone who did something that has been beneficial to the *Guinea Pig Zero* project since the release of Issue #7. You all know who you are and what you did. I've given credit to the writers, artists, and photographers whose work ap-

pears here, as best I knew how. Readers who sent in clippings are, as always, the life-blood of this journal. The input I get from my brother and sisters in blood & urine, (my fellow guinea pigs) is the reason for its existence.

Statement of Purpose *Guinea Pig Zero* is an occupational jobzine for people who are used as medical or pharmaceutical research subjects. Its various sections are devoted to bioethics, historical facts, current news and research, evaluations of particular research facilities by volunteers, true stories of guinea pig adventure, reviews, poetry and fiction relating to the disposability of plebeian life. The journal seeks contributions, and wishes to be useful to human guinea pigs while also being informative to the general public. The editor believes that ethical questions relating to human research are within the moral domain of human research subjects. The title is loosely derived from the term "patient zero," which named an early AIDS victim whose unpredictable behavior became a wild card in the efforts by doctors to control the epidemic. More benevolently, this journal keeps in mind that we, the volunteers, can and should maintain an awareness and a will, because if we do not we'll fall victim to the evil uses devised for us by scientists who forget that we and they are of the same species.

Sinclair Lewis summed it up well, in the voice of a fictional character, in 1925: "*There isn't much I can do now —these doctor Johnnies have taken everything out of my hands—but as far as possible I shall certainly prevent you Yankee vivisectionists from coming in and using us as a lot of... sanguinary corpses.*"

Note: *Guinea Pig Zero* is not an advertiser for research units. The journal does not carry lists of current studies, nor does it publish the telephone numbers of volunteer recruiters. I would also like all of you to remember, before you write, that I (the editor) am not a physician, and if you have a mysterious illness, it's going to be a mystery to me as well. This is especially true in regards to psychiatric disorders.

LES ESSAYEUSES

KEEPING 15TH CENTURY SAVOY SAFE FOR THE RICH

"All around the towns, the sick were penned into barns, cabins, and *chappits*, and they were obliged to stay there under threat of being shot with an arquebus. During this time washers or 'cureurs,' hired by the town, were put to work flushing, perfuming, and washing. They disinfecting the houses, much reinforced by the fumigation of their confection, burning on some wine-dampened hay, which was composed of various drugs, incense, myrrh, alunite, juniper berry, etc., crushed together with saltpetre and gun powder.

"Having closed all the doors and windows, the washer-man or -woman took a barjoz of lighted straw, made the sign of the cross and invoked the father, the Son, the Holy Spirit, and also Roch and Sebastien, the two saints in charge of the conjuration of plagues[...]

"The infected bedding and linen were cleaned with boiling water or else burned. Fifteen days later, the house was re-opened and a poor woman was installed in it for a few weeks, who was called an 'essayeuse'—she served as a guinea pig—and if she made it through, all was well and the family (or what was left of it) moved their household gods back in."

--From Jean and Renée Nicolas, *La Vie Quotidienne en Savoie aux XVIIe-XVIIIe Siecles*, (Paris: Hachette, 1979), page 123; translated for GPZ by Bob Helms

Notes
chappits: can't find the meaning (probably a corral or an animal pen).
arquebus: an early firearm, similar to a blunderbuss or a crude shotgun.
barjoz: an oblong, bound wand of stalks.

Science or Religion?



"Vaccination" by Diego Rivera: note the similarity to a Christian nativity scene, and the paws of the animal which is being vivisected on the table.



This is a detail from Rivera's 1933 masterpiece "Detroit Industry," a mural that covers a large room inside the Detroit Institute of Arts.

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These Brutal Times We Live In

Editorial by Robert Helms

Many months have rolled by and so changes have taken place in every little feature of the world. From my perspective here in Philadelphia, the changes I have witnessed closely are the facades that have collapsed and blown away forever in places of power and wealth. The ivory towers of medical science stand naked in the sun now that the lawsuit against the University of Pennsylvania (along with three of its physicians, its star bioethics professor Arthur L. Caplan, and doctors from two other institutions) has been filed—and later settled—by the family of their now-famous victim, Jesse Gelsinger, on the day after the first anniversary of his death. Most of this issue of GPZ deals with that case—in a nutshell, they lied to Jesse; they slaughtered him; they did it for the money; then they got away with it. There's no apology, now or ever. Caplan even got himself removed from the case before the settlement.

Another suit was filed against the same university shortly before the Gelsinger suit was settled out of court. This was very long in the works, and filed by the former inmates of Holmesburg prison in Philadelphia, where Dermatologist Albert M. Kligman used the prisoners as a guinea pig clearinghouse for unethical experiments by many researchers (see article, page 5).

Let's turn our attention to the University's gene therapy department, where Jesse died over a year ago, recklessly endangered and killed so that James M. Wilson, M.D. could go from rich to super-rich (see GPZ #7). How can one discuss the sordid tale without vomiting? How can we hear the stand-up comic at the top of the Bioethics world, Arthur L. Caplan, boast that "we thrive on scandal," after the government ordered him to remove his office from the suite owned by the Institute for Human Gene Therapy and Genovo, Inc., which committed the manslaughter on Jesse? The feds had been disturbed by Caplan's role as an ethics expert in the

case, since he was not only the head of Penn's Bioethics Department, but also the in-house ethicist for James Wilson's private firm. \$25,000 of Caplan's salary came to him each year from Genovo. What happens to the stomach when we learn that PENN's laboratories were replete with the most scandalously sloppy practices, which rendered much of their scientific data worthless?

The counts named in the Gelsinger lawsuit were:

1. Wrongful death (caused Jesse agony and death by their reckless, careless, and negligent conduct).
2. Survival action (all the defendants wrongfully deprived Jesse of income and his right to earn a living, by killing him).
3. Strict products liability (Dr. James M. Wilson and his company Genovo, Inc. supplied the adenovirus gene vector, which was unreasonably dangerous, didn't come with adequate warnings on it, didn't come with warnings (from Wilson) of the dangers inherent in using it, gave it to Jesse without telling him or his family about the adverse reactions it caused in animals and humans, —and many other ways in which Wilson knew he was harming Jesse by giving him the vector).
4. Intentional assault and battery, lack of informed consent (PENN and Drs. Batshaw, Wilson, and Raper did not tell Jesse the extent of risk involved in taking the vector; that monkeys had gotten sick and/or died from it; that previous human guinea pigs had suffered serious side effects from it; that Dr. Wilson and the University had a financial conflict of interest in the experiment. Also, they misrepresented the "fact" that the prior subjects had achieved better liver function as a result of the experimental treatment. They also let the vectors used on the animals to sit around the lab getting stale for 25 months, but Jesse's were nice and fresh, making the whole study one big, dangerous mess).

Prison Guinea Pigs Sue PENN, cont'd for use of the discovery.

"Former Prisoners Sue Penn Over Medical Research," by Jeffrey Brainard:
Chronicle of Higher Education, Nov. 3

Nearly 300 former inmates of a county jail in Philadelphia have sued the University of Pennsylvania, charging that they were injured and mistreated during studies of skin treatments and drugs during the 1960's and 1970's. The inmates charge that Penn researchers deliberately exposed them to dangerous substances but told them the experiments were harmless.

The suit, filed in Philadelphia in October, alleges that the university coerced the prisoners into participating, and failed to tell them that Penn stood to benefit financially from commercial products developed from the research.

Besides the university, the lawsuit names Albert M. Kligman, a Penn dermatologist who conducted much of the research and is credited with developing the anti-wrinkle treatment Retin-A; and Johnson & Johnson, the pharmaceutical company that sells skin products that use Retin-A. The company has paid the university millions of dollars in fees



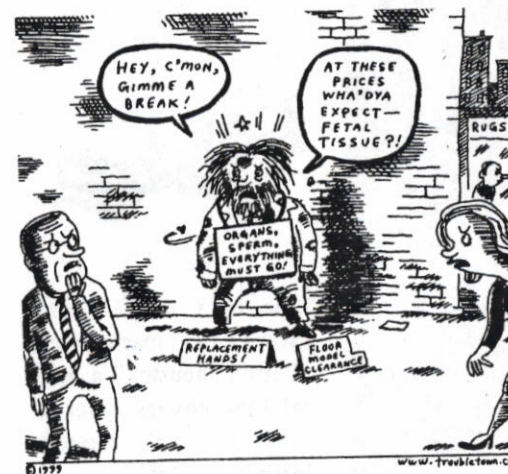
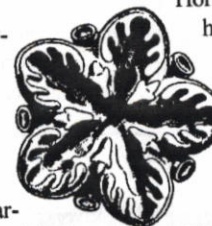
of Skin: Human Experiments at Holmesburg Prison (Routledge), by Allen Hornblum, an adjunct professor at Temple University. Mr.

Hornblum recounted how researchers had performed experiments involving skin treatments that seemed inhumane and that ex-inmates said had left them with scars and bad memories (*The Chronicle*, July 24, 1998).

The plaintiffs also charge that the researchers exposed them to radioactive isotopes and psychotropic drugs, including LSD. Participants were paid small sums.

Many of the plaintiffs are now in their 50's or 60's and are "quite ill" from a variety of maladies, said Thomas M. Nocella, a Philadelphia lawyer who filed the action. He hopes to prove that the experiments played a role. The suit seeks unspecified compensation for the inmates' pain and suffering.

Said Rebecca Harmon, a spokeswoman for Penn: "As we have stated previously, during the 1950's and 1960's, the use of willing, compensated prisoners for biomedical research was a commonly accepted practice by this nation's scientists."



cartoon by Lloyd Dangle

What They Think of Us

By Hobbin A. Smith

Dr. Ola Dale, Anesthesiologist, of the Norwegian University of Science and Technology agreed to do an interview during my most recent study day. Dr. Dale is working on a joint research project on analgesics here at the University of Washington. When Dr. Dale is at Norwegian University, he doesn't have much time to spend with his subjects, he is too busy with meetings and paperwork. During this study he enjoyed being able to spend time getting to know his subjects.

I asked Dr. Dale three questions; what is his opinion of study subjects in general, what do study subjects do that he really appreciates, and what do they do that annoy him.

Most importantly for Dr. Dale is that no harm ever come to any study subject because of any research he is doing. Why? Because he greatly values the contribution study subjects are making when we volunteer to be a guinea pig. During the course of the study he emphasized his appreciation many times.

Dr. Dale valued our opinions. It was important to him that we give him values our willingness to volunteer he hopes that in each of us there is a little bit of altruism in our decision to partici-

pate in the studies. He does not take for granted the contribution that we make and backs this claim up by treating us with respect and bringing us little extras, like chocolates. In particular, he appreciates the subject that follows all of the study requirements and communicates openly any deviations from the protocol.

As for what annoys him? Well,

Dr. Dale considers an investigator/subject relationship to be one that is similar to being in a contract. The investigator has an obligation to fulfill his part of the contract and the subject should fulfill theirs. His biggest issue is compliance and honesty. He recognizes that mistakes occur, after all, subjects are human, but the most important thing is to let him know when a mistake occurs. The data is very important and failing to advise the investigator of deviations can negatively impact the data.

He would like to know, "how do you feel when a study you have participated in ends up not being publishable?"

It was his first time ever talking with a "professional guinea pig" and he had a question for us. He would like to know, "how do you feel when a study you have participated in ends up not being publishable?"

Just when you thought you could trust a politician...

"I didn't go into DrKoop.com to make money. I did it to change the way that medicine is practiced."

—Former U.S. Surgeon General Dr. C. Everett Koop, who, as the chairman of and major shareholder in DrKoop.com, holds more than \$47 million in stock at the company's initial public offering. Of DrKoop.com's several marketing alliances, its deal with Quintiles Transnational Corporation is typical: DrKoop.com agreed to

(New York Times, 9/4/99 —as reprinted in *Ume Reader*, Nov/Dec 2000)

5. Intentional and negligent infliction of emotional distress (they lied to Jesse's father about the risks, so that dad would encourage Jesse to do the experiment, and this is a horrible torment inflicted upon Paul Gelsinger).

6. Common law fraud/Intentional misrepresentation (PENN, Genovo Inc., and their medical mob intentionally misrepresented the experiment in the ways already mentioned in order to induce Jesse to volunteer as their human guinea pig. They knew very well that they were lying).

7. Punitive damages (All the defendants' actions were "intentional, wanton, willful, and outrageous," and were the direct result of their decision to sacrifice patient safety in exchange for the fame and glory that they anticipated for themselves if the adenovirus experiments had been successful. For this, they should pay for what they did).

8. Fraud on the Food & Drug Administration (by doing all the above-stated things, for all the above-stated, rotten motives, they lied to the Feds as well as they did to Jesse and his family, and that means that Penn and its medical mob are a menace to the general public).

Philadelphia Public Ledger, December 5, 1909

point out that Caplan's inclusion among the defendants was a startling new development in the field of bioethics. The *Inquirer* mentioned him only in passing. Remember, please, that the *Inquirer* is the pre-eminent newspaper here in Philly, and it's owned by the same company as owns the only other major one, i.e. the *Daily News*. All through the Gelsinger saga, the *Inquirer* has taken trouble to assist Dr. Wilson and the university in cleaning up the mess. Letters by Caplan and PENN president Judith Rodin are printed, but letters from critics of the University are not (including my own and others by writers with impressive credentials).

Almost every single offense named in the suit had already been established as fact by federal investigators. Arthur Caplan had been evicted from his office due to his conflicts of interest. Genovo and the Institute have been gutted and publicly disgraced by federal authorities.

Will the suit bear fruit, or will the university prevail again? It has prevailed thus far,

POLICE FIND HUMAN HAND Mystery Fades When Evidence of Dissection Is Revealed.

For a few hours yesterday the police of the Belgrade and Clearfield streets station scented a murder mystery and several plain clothes men and specials were detailed to round up suspicious-looking characters. The mystery was started by Policeman Hugh Reed, who found a human hand on a lot at Avramingo and Ontario streets. Reed thought that the hand looked as though it had been recently detached from a body during a struggle. Moreover, it resembled the hand of a girl. Several lofts in the neighborhood were searched in the hope that the remainder of the body might be brought to light, but no more clues were unearthed. Finally one of the specials on examining the hand detected an odor of alcohol. Then it dawned upon the police that the hand had evidently been discarded by a medical student.

Philadelphia Public Ledger, December 5, 1909

The *Post* took care to point out that Caplan's inclusion among the defendants was a startling new development in the field of bioethics. The *Inquirer* mentioned him only in passing. Remember, please, that the *Inquirer* is the pre-eminent newspaper here in Philly, and it's owned by the same company as owns the only other major one, i.e. the *Daily News*. All through the Gelsinger saga, the *Inquirer* has taken trouble to assist Dr. Wilson and the university in cleaning up the mess. Letters by Caplan and PENN president Judith Rodin are printed, but letters from critics of the University are not (including my own and others by writers with impressive credentials).

Good Riddance, Dr. Orne!

Obituary by Harlan Girard

On February 11, 2000, one of the genuine monsters of our time passed to his eternal reward. Or maybe he didn't. One never knows, in dealing with the contract agents of the Central Intelligence Agency (CIA).

Martin Theodore Orne was born in Vienna on October 16, 1927. His father was a surgeon, his mother a psychiatrist. In 1938, the family settled in New York City, and later in Boston. Martin received his M.D. from Tufts University in 1955 and a PhD in Psychology from Harvard in 1958.

Martin Orne's lifelong interest was in hypnosis, and more generally in mind control. His first paper was published while he was still an undergraduate at Harvard: a seminal study called "The Social Psychology of the Psychology Experiment."

In it he demonstrated that the subjects of psychological experiments try to please experimenters by telling them what they think the experimenter is looking for. For 25 years, that article was "one of the three most cited papers in American Psychology," according to a colleague.

This paper provided the intellectual justification for the atrocities committed by the CIA under MKULTRA and subsequent involuntary human experiments. After all, if the subject will respond to cues and give the experimenter what the subject thinks he wants, then it is necessary to take psychological research out of the laboratory and into the streets to get workable results. The paper was also cited by apologists for the Nazi atrocities during World War II: the German people are not inherently cruel. They were

only responding to cues from the Führer.

As a young psychiatrist in practice and something of an expert on hypnosis, Dr. Orne's opinions were eagerly solicited by the CIA. He, in turn, appreciated their non-sense approach to research. The Society for the Investigation of Human Ecology, a CIA-sponsored money-laundering operation based at Cornell University, demanded "no stupid progress reports," Orne recalled for John Marks, author of the classic book *The Search for the "Manchurian Candidate": The CIA and Mind Control*. They not only gave him a grant to support his research in hypnosis, but "as a further sign of generosity and trust, the Society gave Orne a follow-on grant with no specified purpose. Orne could use it as he wished."

"In 1964, as a result of his work for the CIA, Martin Orne was given an appointment at the University of Pennsylvania."

He believed that the money was an investment in his work, and agency officials agreed. "We could go to Orne any time," one of them told Marks, "and say, 'Okay, here is a situation and here is a type of guy. What do you expect we might be able to achieve if we could hypnotize him?' Through his massive knowledge, he could speculate and advise."

In 1964, as a result of his work for the CIA, Martin Orne was given an appointment at the University of Pennsylvania. He eventually became head of the Department of Psychiatry and continued to do classified research on involuntary human subjects for the federal government. I only became aware of Orne late last fall, when I discovered that I'd been living across the street from his own personal money-laundering operation, the Institute for Experimental Psychology, for more

Letters to Guinea Pig Zero

Hello

I heard your interview on *This American Life* and have become absolutely fascinated by this occupation. I liked your honesty and intelligent, early outlook on things. You seem like a normal guy who happened upon an alternative way of making a buck. Your point about the worth of an eight hour day vs. the money that is actually paid to those people was well thought out and rings of truth. Have you been approached by any film-makers? I keep hearing narration overlaying a scene of some shmuck signing up for his fourth turn with some psychoactive drug routine ("brain slur"). I don't have anything to do with Hollywood but I would certainly see the movie of your story!

—David Fulton

David, Of all the publicity I've had since I started this zine, *This American Life* is the one I feel best about. It's been re-run 3 or 4 times, and I hear about it a lot whenever it does. *Irr Glass* and his producers taped more than you heard, and made me sound extra good in the final cut. I actually love that program (i.e. even when I'm not on it).

Movie people have approached me at least a dozen times, and it's come very near to a deal at least 4 times (with lawyers talking to each other). If that ever happens, I'm not sure it will resemble my life, but I'm sure it'll be a nice little adventure.

Bob Helms



The number means that he graduated from the University of Nigeria, College of Medicine, at Enugu, Anambra, in 1984. *100 means that he has no classification. Hall, Gairy Fitzroy; 160 Cherokee Rose Lane, Fairburn, GA 30213; #422-01-1983 IM *40 †20 L1991 (Graduated 1983, St. George's University, School of Medicine, St. George's, Granada, West Indies; Licensed in 1991; Type of practice: Medical education; Certified by the American Board of Internal Medicine).

In other words, they're bottom-of-the-line as far as credentials go. My sister is a nurse, and she once repeated to me a joke she heard a doctor make as he made the rounds at a pediatric intensive care ward. The babies he was looking at had spinafluida (spine is outside the body - fatal deformity) and the first doc said to the other doc, "This one will never go to medical school... and this one here will go to medical school, in Granada..."

Good luck, stay in touch!
In Solidarity, Bob Helms

June 6, 2000: Hey Bob,

I passed a kidney stone. I asked to go to the infirmary and was not allowed to. I went to the doctor next day and he said nothing was wrong with me. He didn't even examine me. I saw a nurse a few hours later and found out that I've had blood in my urine since 1997 and they have not examined me further to determine the

Osprey

in Yuma, and another is based at the Marine Corps Air Station, New River, N.C.

The Marine Corps lists two other crashes during the Osprey's development: a 1991 Delaware accident blamed on gyro wiring problems, and a 1992 Virginia crash that killed all seven people on board after an engine caught fire. Early safety concerns plagued the innovative aircraft and the Bush administration tried to scuttle the project. Builders say design modifications have made today's Ospreys lighter and safer.

"Our objections have been that we're in an arms race with ourselves with the Osprey," said retired Army Lt. Col. Piers Wood of the Center for Defense Information in Washington. "We already have the best helicopter fleet in the world and now we're developing a new concept."

But U.S. Senator Kay Bailey



Hutchison, a supporter from the beginning, said the aircraft is important and especially well-suited for use in rescue operations.

"My belief is that we should make sure that everything is right and make sure that we have this kind of strategic equipment," said Hutchison, R-Texas.

Military planners see the aircraft as a means of getting more troops and pilots safely out of danger zones and enhancing drug interdiction, humanitarian and civilian rescue capabilities. Jointly produced by Bell Helicopter Textron of Fort Worth,

Texas, and Boeing Co., in Ridley Park, Pa., the aircraft can achieve speeds of more than 400 mph and an altitude of 25,000 feet. It's designed to carry up to 24 troops or external loads of 15,000 pounds. The plane was introduced in September and the Marines have ordered 360 Ospreys to be delivered by 2014 at a cost of \$44 million each, Winchester said.

General Pardon Declared for Cavies

Guinea Pigs Will Be Guinea Pigs No More
By CHRIS ADAMS (*Wall Street Journal*)

Score one for the guinea pig.

Actually, score 10,200. That's how many of the rodents could get off scot-free this year as federal regulators change the rules for using animals in chemical tests.

The brown-and-white, 10-inch mammal that has become the dictionary definition of "the subject of any sort of experiment" will no longer be the subject of a test to see if certain chemicals cause an allergic reaction in some people's skin. The test, used by Procter & Gamble Co. and other consumer-products companies, involved painting the guinea pig with a chemical and then injecting a separate chemical into the rodent's body to check for unusual reactions.

The test was effective for its purposes, although the guinea pigs might quibble with the

goal. According to the National Institute of Environmental Health Sciences, 10,200 animals experienced "unrelieved pain or distress" taking part in the test during fiscal year 1999.

The new test is less stressful, less painful—and not performed on guinea pigs. Instead, mice will be used, although government officials were quick to note that the test involves nearly 40% fewer subjects (about 40 guinea pigs were needed for an average test, whereas 25 mice will suffice).

Cuteness apparently helped save the guinea pig. One factor in the decision was that the mouse is "a non-pet animal," a federal spokesman said.



Paul Gelsinger:

Born on June 18, 1981, Jesse Gelsinger was a real character in a lot of ways. Not having picked out a name for him prior to his birth, the name Jesse came to us three days later. When considering a middle name, we pondered James but decided that just Jesse was enough for this kid. His infancy was pretty normal. With a brother 13 months his senior he was not overly spoiled. He crawled and walked at the appropriate ages. When he started talking, it quickly became obvious that this was one kid that would speak his mind and crack everybody up at the same time. He nursed until he was nearly two years old. It wasn't until Jesse was about two years and eight

months old that his metabolic disorder reared its ugly head. Jesse had always been a very picky eater. Since weaning, he would more and more refuse to eat meat and dairy products, focusing instead on potatoes and cereals. After the birth of his sister in late January 1984 and following a mild cold in early March 1984, Jesse's behavior became very erratic over a brief period of time. Since his mother had previously experienced schizophrenic behavior, I was very concerned that Jesse was exhibiting signs of psychosis. His speech was very belligerent... as if possessed. My wife, Pattie, and I took him to see our family doctor. Thinking that Jesse was anemic because of his poor diet and lethargy, he put Jesse on a

Jesse's Intent

high protein diet. It turns out that that was the worst thing for Jesse. Forcing him to eat peanut butter sandwiches, bacon, and to drink milk over the next two days overwhelmed Jesse's system.

On a Saturday in mid March 1984, Jesse awoke, parked himself in front of the television to watch cartoons and promptly fell back asleep. When we were unable to rouse him we became alarmed. His mother called the doctor and insisted that we be allowed to take Jesse to Children's Hospital of Philadelphia, just across the Delaware River from our home near Woodbury, NJ. Upon arrival at CHOP, Jesse was admitted through the emergency room in what they called a first stage coma. He responded to stimuli but would not awaken. After several tests indicated high blood ammonia, the doctor told us that Jesse most probably had Reye's syndrome, which upset us very much. Several hours later they indicated that other tests indicated that this was not Reye's and that they would need to run more tests to determine what was wrong with Jesse. Within a week we had the diagnosis of ornithine transcarbamylase deficiency syndrome. OTC, we were told, was a very rare metabolic disorder. Jesse's form of the disorder could be controlled by



Jesse in Philadelphia, June 22, 1999
--just after screening at PENN

was considered mild and medication and diet.

And so, after eleven days in the hospital, turn to next page

Jesse came home and we hawked everything he ate and made certain he took his medications. From there on Jesse progressed fairly normally, although small for his age. It wasn't until he was age ten that he would need to be hospitalized again for his disorder. Following a weekend of too much protein intake, Jesse's system was unable to rid itself of the ammonia buildup fast enough and he again slipped into a coma. His specialist scrambled to understand how to get him well again, not ever actually having had to treat hyperammonemia. Within five days, Jesse was again well enough to go home, having suffered no apparent neurological damage.

"In September 1998, Jesse and I were made aware by his specialist of a clinical trial being done at the University of Pennsylvania working on what he described as gene therapy for Jesse's disorder. We were instantly interested..."

We scribed as gene therapy for Jesse's disorder. We were instantly interested, but Jesse needed to be an adult, so he was told that he could not participate until age eighteen. That same fall Jesse was stressing his metabolism, as he had never done before. Having recently acquired a part time job and an off-road motorcycle, I saw little of Jesse. As a senior in high school, Jesse had a very busy schedule. Unknown to me at the time, Jesse was having symptoms of his disorder but was trying to hide them. He didn't want restrictions placed on him due to his disorder. I knew that he was inconsistent taking his medications because I rarely had to order them. I spoke with him every other week about his need to take better care of himself. It took him nearly dying to wake him up.

On December 22, 1998, I arrived home in mid-afternoon to find Jesse curled up on the couch. A close friend was with him. Jesse was very frightened. He was vomiting uncontrollably and could not hold down his medications. After about five minutes with him, I determined that I could not manage his recovery. I convinced his pediatrician and specialist that Jesse needed to be hospitalized and placed on intravenous fluids. With his ammonia levels at six times normal, Jesse was in trouble. After no significant changes in his condition by Dec. 24th, the hospital let Jesse go home for Christmas. Listless all day, Jesse crashed Christmas night and was admitted to intensive care where they discovered hypoglycemia, seriously low blood sugar. His specialist felt certain that it was due to one of his medications, l-arginine, and discontinued it. He also decided that Jesse's primary medication, sodium benzoate,

As Jesse entered his teenage years he resisted taking his medications. He felt that he could control his disorder and only took his meds when he didn't feel well. His mother and I had divorced in 1989, two years after our move to Tucson, AZ. Jesse was under my care after obtaining custody of my four children in 1990. At age sixteen Jesse was now taking nearly fifty pills a day to control his illness. Having remarried in 1992, my new wife, Mickie, and I kept a careful watch on Jesse but as he grew older we expected him to take more care of himself. With six children between us we had much to consider. Jesse was being seen at a state funded metabolic clinic in Tucson twice a year to monitor his development and, while not always compliant, he was progressing into adulthood.

In September 1998, Jesse and I were made aware by his specialist of a clinical trial being done at the University of Pennsylvania in Philadelphia. They were working on what he de-

The Few, The Proud, The Guinea Pigs

Four Marine Corps' Planes Grounded

By MICHELLE RUSHLO, Associated Press Writer

MARANA, Ariz. April 10, 2000 (AP)

The Pentagon won't fly the Marine Corps' four remaining Osprey aircraft until investigators determine what caused a fifth to crash during a nighttime training mission, killing all 19 aboard. One grieving mother said her son died as "a guinea pig for these new airplanes."

Marine officials said the MV-22 tiltrotor Osprey did not have a black-box voice recorder but did carry a flight data recorder that federal investigators would study. Investigators spent Sunday reviewing the crash site at Marana Northwest Regional Airport about 30 miles northwest of Tucson, but released few details. There was no immediate indication what caused the Saturday crash, said Capt. Rob Winchester, a Pentagon spokesman. The flight data recorder has not yet been removed from the wreckage, Winchester said today.

The father of one of the victims, Staff Sgt. William Bryan Nelson, said his son considered the plane "experimental" and that it frequently encountered mechanical problems.

"He told me it was so fragile," said William D. Nelson, whose son was among four crew members from a task force based at Quantico, Va. "He didn't think it was very ready to fly yet."

Breaking into tears several times during a phone interview from her home, Patti Weaver said her son, Cpl. Adam Neely, 22, of Windrop, Wash., had left behind a 2-year-old stepdaughter and a pregnant wife. "My heart just breaks when I think about these young men who have so much to give," said Weaver, 48, of Okanogan, Washington.

The Osprey, similar to a turboprop, is part of a new generation of aircraft scheduled to

replace all of the Marines' primary troop-transport helicopters. The military began flying the aircraft six months ago despite lingering questions about costs and safety. Military officials said the downed aircraft was in the process of shifting its propellers from airplane function to helicopter mode when it went down about 500 yards from a runway. It was one of two Ospreys simulating the evacuation of civilians from an embassy in a hostile country, said Marine Lt. Mark Carter, a spokesman for the Yuma air station.

Authorities said the victims include the four crew members from Quantico, Va., 14 Marines from Camp Pendleton, Calif., and one Marine from Marine Corps Air Station-Miramar in San Diego County. Also on board was Keoki Santos, 24, of Grand Ronde, Ore.

His mother, Christina Mercer, said he son had voiced concerns about riding in the Osprey. "He was really, really nervous about the whole thing," she said.

"He was a beautiful, high-spirited, true Marine. He didn't want to just go into the service for four years. He enlisted to be a career man," Mercer said. "And they killed him. They wanted him to be a guinea pig for these new airplanes."

For now, the Marine Corps' four other Ospreys will not be flown until "we can get our arms around what may have happened," Pentagon spokeswoman Capt. Aisha Bakkar-Poe said Sunday. The planes are not considered grounded, which would require an order from Naval Air Systems citing an official cause, she said. Four Ospreys, including the one that crashed, are based



turn to next page

"Hey wait a minute.
I think I know
a guy who did
that study once..."

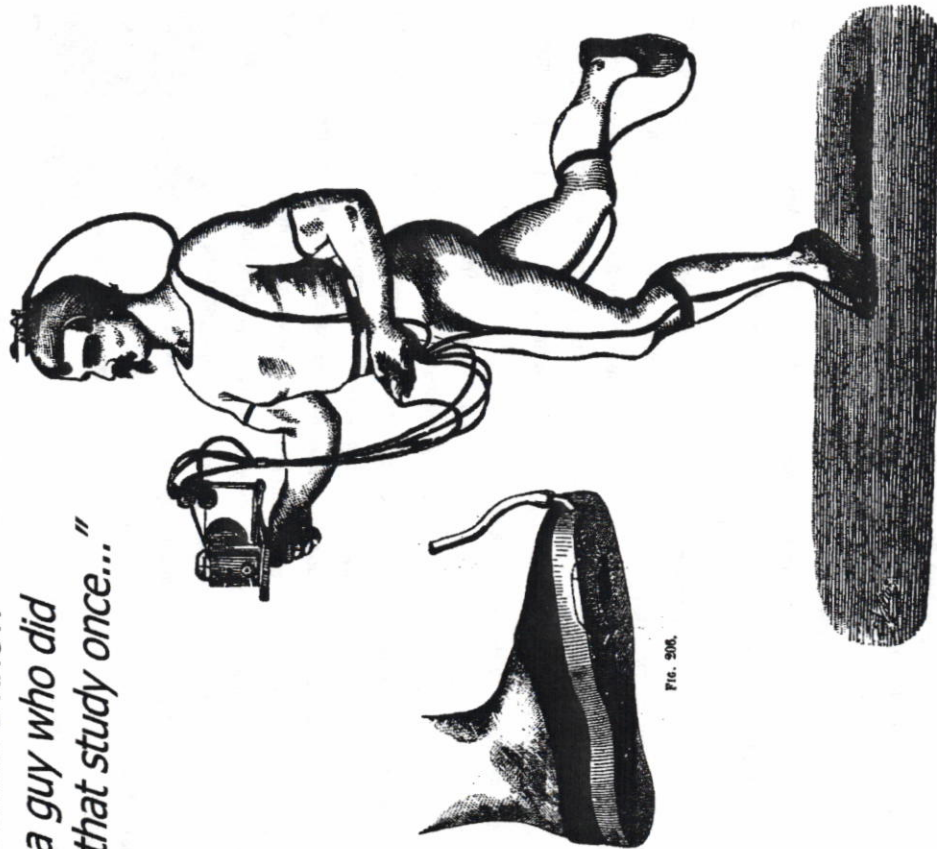


Fig. 200.

"A runner, holding a device in his hand which registers the impacts to the soles of his feet, and carrying on his head another device which registers verticle oscillations."

--from: *Anatomie et Physiologie Animales suives de la Classification*, par Er. Belzung. Paris: Librarie Germer (1896). Caption tr. by GPZ

was not effective enough and ordered that a newer better medication be provided.

Jesse recovered well enough to be placed in a regular room at the hospital but his ammonia levels refused to drop. I was staying in the hospital at Jesse's side day and night. Two days after Christmas, on a Sunday afternoon, Jesse and I had a conversation about how he was doing. I described to Jess how it seemed that he was stuck up a tree, not knowing whether he was going to climb down or fall out. I went home to be with the rest of my family and sleep in my own bed for one night. Jess called me at about 11:00 PM and said, "Dad, I fell out of the tree".

He was again vomiting uncontrollably. I rushed back to the hospital and spent a heartrending two days trying to help my son through his crisis. On Monday, I discovered that the insurance company was balking at paying for Jesse's new medications and that they had not been shipped. I told the pharmacist to purchase the new medications

(\$3300 for one month's supply) with my credit card and that I would deal with the insurance company later. The insurance company relented at that point and authorized the medications and they were ordered on Tuesday. By Tuesday afternoon, Dec. 29, Jesse was so listless that I grew very alarmed that he would not get well.

At 5:00 PM Jesse's vomiting returned and he was becoming incoherent. I moved into the hall to get help. There I found his pediatrician examining his chart. I summoned him to his room and while he called in the intensive care doctor, I called my wife and told her to come im-

mediately. Jesse's aunt and grandmother arrived for a visit only to find Jesse in a crisis. Mickie arrived and together we held Jesse while they prepared a bed for him in intensive care. The intensive care doctor, seeing Jesse's deteriorating condition and believing Jesse always mentally impaired, inquired if life support would be appropriate. It was then that I realized that these people had not known Jesse well, and I explained that the loss of mental faculties that they were seeing was not Jesse's normal state at all. Jesse developed tremors and began to vomit. Suddenly he just stopped. I whispered to Mickie, "He's still breathing, isn't he?" I asked Jesse's pediatrician



Cartoon by Tony Auth

to check him. After placing his stethoscope on Jesse's chest for a few moments he looked to the nurse present and told her to call a code blue. We were whisked from the room, while they intubated and manually ventilated Jesse and took him to intensive care. We were distraught, believing Jesse to be near death. After fifteen minutes they indicated that they were getting him under control, that his heart never stopped.

For two days Jesse lingered in an induced coma to allow the ventilator to control his breathing. He weighed in at only ninety-seven pounds, down from his healthy weight of one

hundred twenty pounds. His old medication only partially lowered his ammonia level. On Thursday morning Jesse's new medications arrived.

Through a gastrointestinal feed, they gave Jesse a special nutritional formula containing his new medications. Within twenty-four hours, Jesse's ammonia levels started falling. We waited at his side as he began to regain consciousness. His first conscious act was to motion us to change the television station... Jesse was back. Within a day Jesse was out of intensive care with ammonia levels at normal levels, something he had never known his entire life. He was ordering and eating food like a teenager... again something he had never experienced.



Jesse the High School senior, earlier in the year of his death

We were ecstatic. When his specialist came to see him, I shook his hand and told him that he had a medical miracle on his hands. A week after nearly dying Jesse was back in school full time with a newfound zeal for life.

By early February 1999 Jesse had recovered enough strength to consider returning to work but he came down with a serious case of influenza. Because illness often triggered Jesse's metabolic disorder, I stayed home to keep an eye on his condition. Jesse was kind enough to pass the bug on to me. It was the sickest I'd been in twenty years with fever for six days and fatigue for four weeks. Jesse recovered within a week and was back in school. I had him tested twice while he was ill and his ammonia level only slightly elevated... the new meds were working wonderfully.

Near the end of February Jesse returned to his part-time job as a courtesy clerk at a supermarket three miles from our home. On Sat-

urday the 27th he called me at 11:00 p.m. for a ride home. I picked him up in my work van and on the way home we had a faithful conversation.

I had been asking Jesse to find out if his job would offer him medical insurance once he graduated from school in May. Being a very typical teenager he had done nothing to inquire and I told him in no uncertain terms that he needed medical insurance if he didn't intend to continue his education. At the time we believed that Jesse would not be covered under our insurance once he left school. Jesse rarely raged at his illness but this time he flung a half-full bottle of soda against my windshield while cursing his disorder.

In anger I gave him a backhand punch to the shoulder and chastised him. Only two blocks from home Jesse in anger flung open the door and told me he was jumping out. I said "Whoa, wait until I stop." As I was coming to a stop he gave me a look like he was jumping and went out the door. All I could envision was Jesse falling under the van and me running him over. Sure enough, even though I had nearly stopped, he fell. As I stopped I could hear him screaming that I was on his arm. Now, my van is a work van loaded with tools and weighing six thousand pounds. Thinking "Oh God, No!" I threw the van in park and raced around the back of the van to find Jesse's right arm and elbow pinned under my right rear tire. Making certain that his body was clear, I rolled the van forward off his arm. The kid was crying in agony. As I cradled him in my arms, I cried, "You idiot, what were you thinking" and then "Jesse, I'm sorry." Begging me not to move him, I knew he would need an ambulance. His arm was a red mess from

HALIOTUS



N the year 54 A.D., a certain Agrippina was the last wife of the Emperor Claudius in Rome. Her son by an earlier husband was the famous Nero. Being the daughter of royalty herself, and shrewd in the cruel ways of palace life, she wanted only the best for her boy. This meant that she needed to ensure that he would inherit the throne, rather than Claudius' other son by an earlier wife. The historian Gaius Cornelius Tacitus, who was born shortly after the events described here, gives the details of Agrippina's careful handling of this important political business. The tale involves a professional poisoner, a physician, and the emperor's taster. A taster was a slave who tried each dish, demonstrating that everything the ruler ate was delicious, unspoiled food, and that it had not been poisoned.

Halotus, the taster in this scene, reminds us of the healthy human research subject of today's drug research, except for his most personal feature. Readers can assign modern counterparts and motives to the other players for themselves, but it seems clear that the plan, which turned out to be quite successful, would have failed had Halotus not been recruited to the conspiracy.

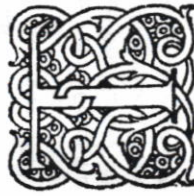


"Agrippina had long decided on murder. Now she had the opportunity. Her agents were ready, but she needed advice about poisons. A sudden, drastic effect would give her away. A gradual, wasting recipe might make Claudius, confronted with death, love his son again. What was needed was something subtle that would upset the emperor's faculties but produce a deferred fatal effect. An expert in such matters was summoned—a woman named Locusta, recently sentenced for poisoning but with a long career of imperial service ahead of her. By her talents, a preparation was supplied. It was administered by the eunuch Halotus, who habitually served the emperor and tasted his food.

"The poison was sprinkled on a particularly succulent mushroom. But because Claudius was torpid—or drunk—its effect was not at first apparent; and an evacuation of his bowels seemed to have saved him. Agrippina was horrified, but when the ultimate stakes are so alarmingly large, immediate dispute is brushed aside. She had already secured the complicity of the emperor's doctor Xenophon; and now she called him in. The story is that, while pretending to help Claudius vomit, he put a feather dipped in a quick poison down his throat. Xenophon knew that major crimes, though hazardous to undertake, are profitable to achieve."

--from Tacitus, *Annals*, book 12.
Michael Grant translation.

THOMAS FORSTER



HE theories of Luigi Galvani made the British headlines in December, 1802, when in the presence of their Royal Highnesses The Prince of

Wales, the Duke of York, the Duke of Clarence, and the Duke of Cumberland, Galvani's nephew, disciple and ardent defender, Professor Giovanni Aldini of Bologna University, applied a Voltaic pile connected by metallic wires to the ear and nostrils of a recently killed ox-head. At that moment, 'the eyes were seen to open, the ears to shake, the tongue to be agitated, and the nostrils to swell, in the same manner as those of the living animal, when irritated and desirous of combating another of the same species.'

"But Professor Aldini's most notorious demonstration of galvanic electricity took place on January 17, 1803. On that day he applied galvanic electricity to the corpse of the murderer Thomas Forster. The body of the recently hanged criminal was collected from Newgate where it had lain in the prison yard at a temperature of 30 degrees Fahrenheit for one hour by the President of the College of Surgeons, Mr. Keate, and brought immediately to Mr. Wilson's Anatomical Theatre where the following experiments were performed. When wires attached to a pile composed of 120 plates of zinc and 120 plates of copper were connected to the ear and mouth of the dead criminal, Aldini later reported, 'the jaw began to quiver, the adjoining muscles were horribly contorted, and the left eye actually

opened. When the wires were applied to the dissected thumb muscles they "induced a forcible effort to clench the hand"; when applied to the ear and rectum, they "excited in the muscles contractions much stronger...The action even of those muscles furthest distant from the points of contact with the arc was so much increased as almost to give an appearance of re-animation. "And when volatile alkali was smeared on the nostrils and mouth before the Galvanic stimulus was applied, "the convulsions appeared to be much increased...and extended from the muscles of the head, face, and neck, as far as the deltoid. The effect in this case surpassed our most sanguine expectations." Aldini exulted, and remarkably concluded that "vitality might, perhaps, have been restored, if many circumstances had not rendered it impossible." Here is the scientific prototype of Victor Frankenstein, restoring life to dead bodies.

In further experiments conducted by Aldini in 1804, the bodies of human corpses became violently agitated and one even raised itself as if about to walk; arms alternately rose and fell; and one forearm was made to hold a weight of several pounds, while the fists clenched and beat violently the table upon which the body lay. Natural respiration was also artificially reestablished and, through pressure exerted against the ribs, a lighted candle placed before the mouth was several times extinguished."

—from Anne K. Mellor, *Mary Shelley: Her Life, Her Fiction, Her Monsters* (Methuen, 1988), pp. 105-106.

wrist to upper arm with the elbow area gouged out. The tire print was evident on the underside of his arm. As I began to think about seeking help, a woman who had witnessed what happened while driving from the other direction asked if she could help. I told her to please call 911 and she drove off to do so. A neighbor, hearing the commotion, came out and offered his help. Another passerby offered me his cell phone and I called my wife. Within minutes the paramedics arrived, strapped Jesse to a gurney and whisked him off to the hospital. After the police informed me that I had done no wrong, that I could not control his actions, it was all I could do to drive the one block left to home. I had been there to help Jesse through his near death experience in December and through a serious bout with the flu only to nearly end his life in an accident.

Shaking and emotional, my wife, Mickie, drove me to the hospital. Jesse was okay; he hadn't even broken his arm! While suffering

extensive road rash and a serious wound to his elbow he recovered full use of his arm following two days in the hospital and a month of physical therapy. I was an emotional wreck for a week following the accident. This kid was something else. His sister told him that if he caused me to have a heart attack she was going to kill him. A month later I got word from our insurance com-

pany regarding Jesse's status if he did not continue his education. He was covered until age twenty-five as long as he remained our dependent. I joked with him that I had run him over for nothing. He was proud of his war wound with dad. God, what a relief to see this kid bounce back again.

In early April 1999, Jesse again had an

appointment at the metabolic clinic. While there, the subject of gene therapy and the clinical trial at the University of Pennsylvania came up again. Jesse and I were both still very interested. I informed the doctor that we were already planning a trip to New Jersey in late June, that Jesse would be eighteen at that time and to let Penn know we were interested. I received a letter from Penn in late April firming things up. By late May our visit was set. We would fly in on June 18th and he would be tested on the 22nd. Jesse was none too happy about flying in on the 18th, that was his birthday and he wanted to party with his friends. A few days later he told me it was okay to fly on his birthday. I told him that it was a good thing since I had already bought the tickets for all six of us a month earlier.

So on Friday, June 18, 1999, Jesse with his three siblings, PJ (age 19), Mary (15), and Anne (14), and

"On Tuesday, June 22nd, we all headed over to Philly to meet with the clinical trial people. We arrived a few minutes late because of a wrong turn on the expressway only to discover that they weren't ready for us."

Mickie and I boarded a plane to take us down a path we never imagined. We had a party for Jesse that night at my brother's house. We had a reunion with ten of my fifteen siblings and extended families that Sunday. It was great to see everyone. The kids got to meet cousins they hadn't seen in twelve years. Jesse's cousins nicknamed him Captain Kirk for the way he struck the volleyball with a two-handed chop. This was turning into a great vacation.

We hung out on Monday and on Tuesday, June 22nd, we all headed over to Philly to meet with the clinical trial people. We arrived a few minutes late because of a wrong turn on the expressway only to discover that

they weren't ready for us. The nurse in charge rounded up Dr. Raper and after a 45-minute wait we were all ushered into a hospital room to go over consent forms and discuss the procedures that Jesse would undergo.

Dr. Raper described the technique that would be used: Jesse would be sedated and two catheters would be placed into his liver; one in the hepatic artery at the inlet to the liver to inject the viral vector and another to monitor the blood exiting the liver to assure that the vector was all being absorbed by the liver. He explained the dangers associated with this and that Jesse would need to remain immobile for about eight hours after the infusion to minimize the risk of a clot breaking free from the infusion site. Dr. Raper also explained that Jesse would get flu-like symptoms for a few days. He briefly explained that there was a remote possibility of contracting hepatitis. When I questioned him on this, he explained that hepatitis was just an inflammation of the liver and that the liver was a remarkable organ, the only organ in the body with the ability to regenerate itself. In reading the consent form, I noticed the possibility of a liver transplant being required if the hepatitis progressed. The hepatitis seemed such a rare possibility and the need for transplant even more remote that no more alarms went off in my head.

Dr. Raper proceeded to the next phase and what appeared the most dangerous aspect of the testing. A needle biopsy was to be performed of Jesse's liver one week after the infusion. Numbers explaining the risks of uncontrolled side effects were included. There was a one in ten thousand chance that Jesse could die of the biopsy! I

"He briefly explained that there was a remote possibility of contracting hepatitis. When I questioned him on this, he explained that hepatitis was just an inflammation of the liver and that the liver was a remarkable organ..."

said to Jesse that he needed to read and understand what he was getting into, that this was serious stuff. The risks seemed very remote but also very real. Still one in ten thousand weren't bad odds in my mind. There would be no benefit to Jesse, Dr. Raper explained. Even if the genes worked the effect would be transient because the body's immune system would attack and kill the virus over a four to six week period.

After our forty-five minute conversation with Dr. Raper ended, Jesse consented to undergo the five-hour N15 ammonia study to determine his level of enzyme efficiency. Many vials of blood were taken before Jesse drank a small vial of N15 ammonia.

This special isotope of ammonia would then show up in Jesse's blood and urine. The rate at which it was processed out of the body would determine Jesse's efficiency. Going into this study we were aware that Jesse's efficiency was only 6% of that of a normal person. After waiting with Jesse for two hours we all decided to head out to Pat's Steaks for lunch and tour South Street for a few hours. On our return to the hospital, Jesse was done and ready to go. It was now mid-afternoon and we decided to see the Betsy Ross house and Independence Mall. After checking out the Liberty Bell, the kids wanted to see the Rocky statue, so we headed over to the Art Museum. Four of us, Jesse, PJ, Mary and me, raced up the steps Rocky style (we had watched the movie the night before). Finding only Rocky's footsteps, we learned that the statue had been moved to the Spectrum. So, we headed over to Patison Avenue. A Phillies' game was about to start so I stayed in our rented Durango while the kids had their pictures taken by Mickie. It was a fun time for everyone, especially Jesse. He was starting to feel good about what he was doing. This was his thing and he

agony. The three of us could hardly hold down the armless, legless body, which twisted and jumped around on the bed like a big worm.

"I named a begonia after him, a sort of freak I got three years ago that only had three petals. You understand. I named it 'Le Triomphe du Mutilé Deland.' Only thing is, it doesn't reproduce by seeding. That's annoying!"

I watched the old begonia grower closely, after he finished his tale, and the soul of the horticulturist is so complex that I couldn't tell whether he was making fun of us or if the episode had really happened. At any rate, I was quickly distracted by a rosebush grower with a beard and an enormous gut, who claimed everybody's attention by saying:

"Well, then! Myself, I've seen something even worse than that. I've seen..."



chrysanthème

Guinea Pig Job Sharks, (continued from page 28...)

a product. This includes all sorts of local doctors who have looked for patients with a condition or disease, focus groups that ask for reactions to advertisements, fertility clinics, and a few actual research units, which actually are looking for healthy volunteers. The average young party animal, looking for sex and drug use as a paying job, will find the book a great way to squander \$20 and then to squander more time and money by making calls to disconnected lines and medical offices that are not looking for lazy, drunken college students.

The site runs a disclaimer: they don't recommend any particular products or services, and they only sell the book, with its contact information. They're not responsible for whatever happens between you & the people running studies. How about that! No ethics board in the picture, then? I guess if the simple rules of Capitalism were applied to medical science across the board, we'd be seeing some pretty funny informed consent forms: "Try out our new cancer drug - meet sexy girls!"

These cheap hucksters want you to believe that

Notes:
*Jean-Philippe Gury and Bob Helms edited this translation.

¹ The story appeared in *Le Journal* (Paris), January 5, 1896, just after the Leboudy affair: the son of a rich sugar manufacturer had died, simply because military doctors refused to believe he was ill.

² Leon Bloy (1846-1917) was a French Catholic writer and social reformer known for his extremely bitter attacks on corruption in the Church. His works include *The Woman Who Was Poor* and *Salut par les Juifs* (Tribute to the Jews). He and Mitbeau contributed work to some of the same journals.

³ Adolphe Thiers (1797-1877), the Prime Minister who oversaw the bloody repression of the Paris Commune, which included the summary execution of some 30,000 lower-class civilians.

⁴ Félix Faure (1841-1899) was President of France at the time when this story appeared. Mitbeau is illustrating horticulturists as tending towards conservative politics.

the life of a human research subject is as easy as hanging out at a frat party. They state on the site that they've been seen on Fox TV, Oprah, and Discovery. They have this local number in Philadelphia, which refers you (after listening to a recorded sales pitch that repeats what's on the website) to another number in Washington D.C.. This speaks of a substantial and well-funded, but hard-to-trace operation, which sells largely useless books by appealing to one's basest instincts, and which pushes all the lame, cheap myths about guinea pigging to suckers. They even re-chew the ancient anecdote about film director Robert Rodriguez getting started with this kind of income! They want to be sure that their customers are only the most stupid people on Earth. *Buy this book, get free booze & dope, get paid to have sex, start a glamorous career in Hollywood!* It reminds me (again) of the similarities between the sex business and the recruitment of human research subjects. How does this "National Research Group" and its selling tactics differ from phone-sex numbers, penis-enlargement ads, or on-line Viagra ads?

stopped passing by on that road. And since they had nothing to eat, they spread out into the countryside, into people's gardens, asking sometimes, but usually just taking. Well, everyone's got to live, after all, even soldiers! So then, try to get any planting done, under such conditions! Listen, I'm telling you, one night some irregulars, who spoke Spanish, invaded my establishment and took my begonia bulbs, which they cooked in a pot by the side of the road, with some biscuits. Ah, what a time! What a time for planting, Lord Jesus! One day, we learned from some routed troops that they were fighting at Lorges, at Beaugency, God, all over! Things didn't seem to be going very well. Then we started seeing bands of cows and troops of sheep being chased by us at saber-point, and the troops never stopped retreating toward Le Mans. Finally,



Cobaye

we heard the cannons approach. The situation was really awful, because there were no provisions left in Vendôme. You couldn't have found the smallest end of a sausage in any of the butcher shops. As for my food reserves, they were tapped out, and I was digging into my last pot of goose pâté. Naturally, my greenhouses were defunct, and I didn't even have anything to fill my spirit-lamps for my glass-frames. You try planting under those conditions.

"You bet!" agreed one horticulturist. "It was the same for me, with my gladiolae. The Prussians grubbed them up—over three hundred varieties, all named, and they made them into soup! It's true!"

"No doubt," pronounced a chrysanthemum grower, "but what do you want? War is war."

The begonia grower went on. "One morning, they rang at the gate of my establishment. A cart was parked out front, a poor, requisitioned cart, all falling apart and covered with a ripped-up canvas. A scrawny horse, led by an even scrawnier soldier,

then a fever took him, and he died in a horrible

way. I brought the cart into the courtyard, in front of the door of my house and, having called to my wife and daughter, I got ready to unload, with the help of the soldier, the wounded man, who, bedded down on a cushion of straw and wrapped in blankets, moaned, "Ah, boss, boss, boss!" But how stupefied I was, when I uncovered him, to handle him more easily.

"Your arms! What have you done to your arms?" I cried.

"They cut them off?" Delard answered.

"And your legs? Where are your legs?"

"They cut them off of me, too," the poor devil groaned. At first I thought it must be a joke, but there was the evidence, right in front of me. Delard no longer had any arms, nor any legs. He was a trunk, a living, moaning trunk that I had no idea how to deal with. The shock I felt before that body, so horribly mutilated, was so great that I fainted like an animal, next to Delard, in the sad little wagon. God only knows whether I'm really so faint-hearted! Anyway, my friends, Delard lived on for four days, at my house, in that condition! What bothered him the most was that he couldn't gesture anymore. And still he talked about his arms and legs as if they were still attached to his body. Sometimes, he would "point" to something with his missing arm, and say to me, "there, over there, boss!" In the end, you know what his last words were? "Now how will I manage to water the plants?"

had a chance to help. The following day we toured New York City. Everybody got to pick a place to visit. Jesse chose FAO Schwartz toy store where he bought four Pro Wrestling action Figures. We all had a great day finishing with the Empire State Building and the Staten Island Ferry.

Four weeks later, back in Tucson, we received a letter addressed to Mr. Paul Gelsinger and Jesse. It was from Dr. Mark Batshaw confirming Jesse's 6% efficiency of OTC and stating that they would like to have Jesse in their study. I presented the letter to Jesse and asked him if he still wanted to do this. He hesitated about a moment and said yes. Dr. Batshaw called about a week later to follow-up his letter and spoke to Jesse briefly. Jesse told him that he would need to call back and talk to me and explain everything. Jesse was deferring to me to understand this and Dr. Batshaw was well aware of that. When I spoke to Dr. Batshaw we discussed a number of things. Since they had forgotten to include the graph showing Jesse's N15 results he faxed it to us. I asked if Jesse was the least efficient patient in the study. Dr. Batshaw explained that he was. Dr. Batshaw steered the conversation to the results they had experienced to date. He explained that they had shown that the treatment had worked temporarily in mice, even preventing death in mice exposed to lethal injection of ammonia. He then explained that the most recent patient had shown a 50% increase in her ability to excrete ammonia following gene therapy. My reaction was to say, "Wow Mark! This really works. So, with Jesse at 6% efficiency you may be able to show exactly how well this works." His response was that that was their hope and that it would be for these kids. He explained that there were another 25 liver disorders that could be treated with same technique and that overall these disorders affected

about one in every 500 people. I did some quick math and figured that's 500,000 people in the U.S.A. alone, 12,000,000 worldwide. I dropped my guard. Dr. Batshaw and I never discussed the dangerous side of this work. When I presented to Jesse what Mark Batshaw had to say he knew the right thing to do... he signed on to help everybody and, hopefully, himself in the long run. The plan was for him to be the last patient tested and was tentatively scheduled for mid October.

So, by late July 1999 Jesse had a new focus for his life but he had other priorities also. He had just gotten a tattoo on the back of his right calf. Of course, he didn't discuss it with me first and had used the money he owed me to get it done. I had just bought him a used street motorcycle as a graduation present and he was getting his driver's license, which he obtained on August 21. It was so great to see him grinning ear to ear as he drove

drive off on his bike for the first time. We saw little of Jesse over the next two weeks. If he wasn't working, he was out riding with his buddy, Gar, or spending the night at a friend's house. He was still living at home and paying \$35 a week for rent and \$15 a week to pay back for the bike insurance that we had fronted for him. This kid was really living and we were so proud of him.

In mid-August we heard from Penn that they were having trouble scheduling their next patient and were wondering if Jesse would

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be available in September. I explained that I he was my hero. As I drove off to work, I thought would have to check with him. He okayed it and of him and what he was doing. I started considering how to get him some recognition. Little did I know what effect this kid was going to have.

Jesse called us that night using his phone card. He was well, had a little mix-up with the cabbie about which hospital to take him to. The cabbie was cool about it though, he said. Reminded him of a scary version of James Earl Jones. Jesse was to have more N15 testing the following day and again on Sunday before the actual gene infusion on Monday, September 13. Saturday was an off day and he would be able to leave the hospital. Two of my brothers had arranged to visit with Jesse and that had put me at ease about not going. Jesse had a blast with his uncle and cousins on Saturday and a good visit with his other uncle and aunt on Sunday. Mickie and I spoke with Jesse every day and his spirits were good. He was apprehensive on Sunday evening. Dr. Raper had put him on intravenous medications because his ammonia was elevated. I reasoned with him that these guys knew what they were doing, that they knew more about OTC than anybody on the planet. I didn't talk with the doctors; it was late.

I received a call from Dr. Raper on Monday just after they infused Jesse. He explained that everything went well and that Jesse would return big hug and as I looked him in the eye, I told him



Artwork by Dusan Petricic

The Torso

By Octave Mirbeau (1848-1917)
Translated for GPZ by Ann Stierzinger*

The other night, they were talking about military doctors—a popular subject at the moment—and everybody had an anecdote to tell. Naturally, they were all shocking, and never, I believe, have I ever heard so many horrors at one sitting. For the lack of a better phrase, it turned my stomach. I have to confess that this was going on at a gardeners' banquet, and gardeners, by nature, are inclined to enthusiasm and even to exaggeration. I'm not going to explain the reasons for this psychological phenomenon, as they would take me too far off the subject. Didn't Leon Bioy² write something about the "complicated soul of the horticulturist?"

"Yes, Sir, I saw it myself," said a big devil of a seedling-grower. "I saw a surgeon one night, in a miller's cart, amputating a man with a dragon's saber, because he'd lost his medical kit—God knows where!"

"Why didn't you lend him your grafting knife?" Someone said. They all burst out laughing. And if the horticulturist has a complicated soul, he has, inversely, an easy and raucous laugh. When the gaitery solicited by this professional quip has settled down a bit,

"All right! But I've seen something to top that!" declared a begonia grower who had remained silent until that moment, chomping a dead cigar with the big yellowed teeth between his jaws.

He was a little fellow with wrinkled, clean-shaven skin, an obstinate forehead, and rough hair whose thick, sausage-like fingers didn't seem to handle the light, mysterious seeds of plants, nor to play with the pistils of flowers.

There was suddenly a religious silence. The little man was one of the leading lights of French horticulture, and they admired him very much for having known, thanks to judicious plantings and well-reasoned selections, how to add an artificial and composite ugliness, which everyone there felt could never be surpassed, to the natural ugliness of the begonia. Everyone felt, also, the story he was about to tell must top the others in horror, since the little fellow never spoke in vain, and when he didn't have anything to say that would top what had been said already, he would be quiet, no doubt thinking up even scarier hybrids.

"Yes, I've seen something to top that!" he repeated. "I've seen... Well, let's begin at the beginning."

Some of the horticulturists got up from the long table and gathered, respectfully, behind the narrator, who recounted the following:

"It was during the War of Seventy, Vendôme, and I hadn't yet developed my famous begonia the 'Deuil de M. Thiers,'³ for a good reason, of course, because M. Thiers wasn't dead yet."

One of the gardeners huddled behind the old planter, whose gestures, I have to say, weren't the least bit dignified, interpreted:

"Yeah, that was some development, Begonia that 'Deuil de M. Thiers.' It was the beginning of a whole big series, and without that, we'd never have had the 'Triomphe de Président Fauré,'⁴ without which, hell!" He completed his sentence with a grand, circular gesture.

This homage having been rendered unto the abilities of the old—shall I say, *begoniaeur*—he went on:

"My establishment was situated two hundred meters out of town, on the road to Longes. Ah, what an era! Good Lord! Soldiers, soldiers, soldiers. For over two months, they never



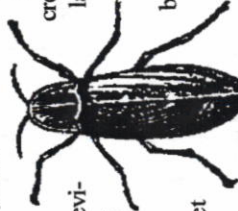
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Franklin's Closet ...continued

time in back of the house. In 1772, Sally Stevenson had married a young physician, William Hewson, and he lived with the family (and Franklin) for two years.

Scientists examining the bones say they look like they came from the dissection table, due to evidence of sawing and drilling characteristic of medical tools of the day. Marcia Balisciano, director of the Craven Street House, informed GPZ editor

Bob Helms and myself on a recent visit that animal bones showing the same sawing and drilling had also been recovered from the garden in front of the house. Hewson was a respected physician, but dissection of human bodies was prohibited at the time of his anatomy school.



1774, after cutting himself during a dissection. Researchers speculate that Franklin probably knew what was going on in the anatomy school, but that it was unlikely that he participated. His scientific interests ran more to physics and natural science than to anatomy and medicine.

Farewell, Brave Baby



9-month old Gage E.

Stevens, a Pittsburgh area baby, died while serving as a guinea pig just before Thanksgiving, 1999. Under investigation was the use of Propulsid in children to prevent stomach acid reflux. He is one of the 19 cases reported by FDA in which babies died while taking Propulsid.

Sage Stevens (1999-1999)

Good Riddance (continued)

than five years. He died before I had the opportunity to confront him —or maybe he didn't.

The point that most Americans fail to grasp is that the CIA is a criminal organization. The activities they engage in overseas are crimes under US law and are crimes under the laws of most of the countries where they operate. But unlike the usual motive of organized crime, which is money, ever?

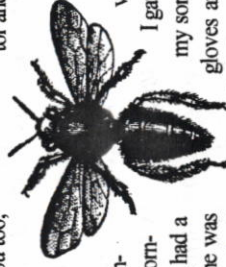
to his room in a few hours. I discussed the infusion and how the vector did its job. Dr. Raper didn't like the word invade when I explained what I thought the virus did to the liver cells. He explained that if they could affect about one percent of Jesse's cells, that they would get the results they desired. Mickie and I spoke with Jesse later that evening. He had the expected fever and was not feeling well. I told Jesse to hang in there, that I loved him. He responded, "I love you too, dad." Mickie got the same kind of goodbye. Little did we know it was our last.

I awoke very early Tuesday morning and went to work. I received a mid-morning call from Steve Raper asking if Jesse had a history of jaundice. I told him not since he was first born. He explained that Jesse was jaundiced and a bit disoriented. I said, "That's a liver function, isn't it?" He replied that it was and that they would keep me posted. I was alarmed and worried. My ex-wife, Pattie, happened to call about twenty minutes later and I told her what was going on and she reminded me that Jesse had jaundice for three weeks at birth. I called Penn back with that information and got somebody who was apparently typing every word I said. That seemed very unusual to me. I didn't hear from the doctors again until mid-afternoon. Dr. Mark Batshaw called and said Jesse's condition was worsening, that his blood ammonia was rising and that he was in trouble. When I asked if I should get on a plane, he said to wait, that they were running another test. He called back an hour and a half later and Jesse ammonia had doubled to 250 micromoles per deciliter. I told him I was on a plane and would be there in the morning.

It's a very helpless feeling knowing your kid is in serious trouble and you are a content away. My plane was delayed out of Tucson but got into Philly at 8:00 a.m. Arriving at the hospital at 8:30 a.m. I immediately went to find Jesse. As I entered thru the double doors into surgical intensive care I noted a lot of activity in the first room I passed. I waited at the nurse's station for perhaps a minute before announcing who I was. Immediately, Drs. Batshaw and Raper

approached me and asked to talk to me in a private conference room. They explained that Jesse was on a ventilator and in a coma, that his ammonia had peaked at 393 micromoles per deciliter (that's at least ten times a normal reading) and that they were just completing dialysis and had his level down under 70. They explained that he was having a blood-clotting problem and that because he was breathing above the ventila-

tor and hyperventilating his blood pH was too high. They wanted to induce a deeper coma to allow the ventilator to breathe for him.



I gave my ok and went in to see my son. After dressing in scrubs, gloves and a mask because of the isolation requirement I tried to see if I could rouse my boy. Not a twitch, nothing. I was very worried, especially when the neurologist expressed her concern at the way his eyes were downcast... not a good sign, she said. When the intensivist told me that the clotting problem was going to be a real battle, I grew even more concerned. I called and talked to my wife, crying and afraid for Jesse. It was at least as bad as the previous December, only this time they had been in his liver. I would keep her posted.

They got Jesse's breathing under control and his blood pH returned to normal. The clotting disorder was described as improving and Dr. Batshaw returned to Washington, D.C. by mid-afternoon. I started relaxing, believing Jesse's condition to be improving. My brother and his wife arrived at the hospital around 5:30 p.m. and we went out to dinner. When I returned I found Jesse in a different intensive care ward. As I sat watching his monitors I noted his oxygen content dropping. The nurse saw me noticing and asked me to wait outside, explaining that the doctors were returning to examine Jesse. At 10:30 p.m. Dr. Raper explained to me that Jesse's lungs were failing, that they were unable to oxygenate his blood even on 100% oxygen. I said: "Whoa, don't you have some sort of artificial lung?" He thought about it for a moment and said yes, that

THE WEIRD OLD DAYS THAT NEVER END

Back in the days when lobotomies were on the way out and Thorazine was the coolest thing since sliced bread, psychiatrists were working hard, trying to find new ways to treat mental illness. The following is a short article from the dime-store periodical People Today, January 12, 1955. It describes experiments in electroshock and hallucinogenic drugs, and it is offered now as an example of why we should never trust medical experimenters at their word, but should always question them and hold their opinions under the lens of our own common sense. We still fall prey to doctors with another plan for the better human mousetrap, but 1955 was an age when physicians were less likely to be questioned by anyone outside their own profession. Stay watchful, lest those days return. —GPZ



A posed image from the contemporary film on mental health, "The Lonely Night."

NEW HOPE FOR THE 300,000 U.S. SCHIZOPHRENICS

In New Orleans at the Tulane University School of Medicine a doctor connects the wires of an electronic machine with wires implanted, through holes bored in the skull, directly in the brain of a human patient.

In Boston at the Psychopathic Hospital another doctor hands a young man a glass of water containing the merest traces of a tasteless, colorless, odorless drug called lysergic acid.

Working with different subjects—the first mentally ill, the other "normal"—and by vastly dissimilar methods, both doctors are aiming at the same goal: to find the causes of, and eventually the cure for, schizophrenia, America's costliest illness. The Tulane doctor, by brain stimulation, establishes communication with a mental victim who has retreated into a dream world. The Boston doctor duplicates, for several hours, the symptoms of a split personality in a sane person; then he converses with his subject and records the talk.

Actually, the two projects are but a trickle in the Niagara of research being directed towards combating mental illness. Dr. William Mahanad, director of the research program of the Natl. Assn. for Mental Health, recently reported on "promising leads" based on 17 NAMIH projects.

"We are now in a position to state that the development and progress of this disease is dependent upon: a) a certain constitutional weakness which some children bring with them

other chaplain, a man a few years younger than me and a Christian, was called in to help me. At this point I was trying to contact my family, my mother to get emotional support. A hospital staffer was very helpful in that respect.

"When we finally got to see Jesse, he was bloated beyond recognition. The only way to be sure it was Jesse was the battle scar with his dad on his elbow and the tattoo on his right calf."

By mid-morning six of my siblings with their spouses had arrived. Mickie's plane just got in before they closed the airport and she arrived by taxi at the hospital. We weren't able to see Jesse until after noon. Dr. Batshaw was stuck on a train disabled by the hurricane. Drs. Raper and Shapiro described Jesse's condition as very grave; that whatever reaction his body was having would have to subside before he could recover. His lungs were severely damaged and if he survived it would be a very lengthy recovery. They had needed to use more than ten units of blood in hooking him up. When we finally got to see Jesse, he was bloated beyond recognition. The only way to be sure it was Jesse was the battle scar with his dad on his elbow and the tattoo on his right calf. My siblings were shaken to the core. Mickie touched him ever so gently and lovingly, our hearts nearly breaking.

With the hurricane closing in and threatening to close the bridges home, my siblings left by late afternoon. My sister and her husband stayed to take us to dinner and drive us exhausted to our hotel. After sleeping for an hour, I arose and felt compelled to return to see Jesse. Leaving Mickie a note I walked the half-mile back to the hospital in a light rain. Hurricane Floyd had skirted Philly and was heading out to sea. I found Jesse's condition no better. I noted blood in his urine. I thought, "How can anybody survive this?!" I said a quiet goodbye to Jesse and returned to the hotel at about 11:30 p.m. I found Mickie preparing to join me. I described Jesse's condition as no different and returned to bed.

he would need to call in the specialist to see if Jesse was a candidate. I told him to get on it. I called my wife and told her to get on a plane immediately. At 1:00 a.m. the specialist, Dr. Shapiro, and Dr. Raper indicated that Jesse had about a 10% chance of survival on his own and 50% with the artificial lung the ECMO unit. Hooking up the unit would involve inserting a large catheter into the jugular to get a large enough blood supply. I said, "50% is better than 10, let's do it." It seemed like forever for them to even get the ECMO unit ready. Jesse's oxygen level was crashing. At 3:00 a.m. as they were about to hook Jesse up, Dr. Shapiro rushed into the waiting room to tell me that Jesse was in crisis and rushed back to work on him. The next few hours were really tough. I didn't know anything. Anguish, despair, every emotion imaginable went through me. At 5:00 a.m. Dr. Shapiro came to see me and said they had the ECMO working but that they had a major leak, that Dr. Raper had his finger on the leak. I quipped that I was a bit of a plumber, maybe that's what they needed. Shapiro returned to work on Jesse and I began to worry for my wife. Hurricane Floyd had made landfall in North Carolina at 3:00 a.m. and was heading toward Philly. At 7:00 a.m. I entered through the disabled double doors into the intensive care area and after noting four people still working on Jesse and another half dozen observing, approached the nurses station get them to see if my wife would get in ok. They agreed to check and asked if I would like a chaplain. I'm a pretty tough guy, but it was time for spiritual help. They at first sent a young woman who I think was Jewish. I guess she felt a bit out of place since I am Christian and an-

Guinea Pig Job Sharks:

How you should NOT look for a study

By Robert Helms

A friend asked me over lunch the other day, "hey Bob, what do you think of this ad in the *City Paper*?" She showed me the back cover of a local free weekly.

"Smoke Pot-Get Paid!" it read, "to \$2,680 Cash! Legal Studies. Private (215) 602-2410 ConfidentialReport.com"

I replied that I'd never needed to answer an ad to find a study, and so I had no real opinions for that area of discussion. The ad, however, was pretty cheesy, so I decided to check the URL and give the phone number a try. As one might expect, it got worse and worse.

Whenever a company hawks its wares by first getting the consumer interested in getting stoned, the warning lights should turn on. This was only the first problem I had with "National Research Group."

I checked the web site, and the first thing I saw was a little sign that changed to several more dangling lures, like "Drink Alcohol, \$1500," and "Safe Sex Research, \$850." There were a few more that referred to sleep studies and memory/personality studies. There was nothing about how, when a subject signs up for a scientific experi-

ment, they will almost always undertake some level of personal risk, and sometimes the risk is considerable. There was nothing about the basic discomforts, such as needle sticks, catheterization, nasogastric intubation, soft tissue biopsies, and urine/feces sample collection. Naturally there were no mentions of the known and expected side effects involved in taking all those other drugs under research (all but one-millionth of the whole lot), such as nausea, headaches, dryness of mouth, etc.. Not a word about the unknown problems that scientists are paying the guinea pig to find—the whole point of any Investigational New Drug study, including psychiatric episodes, skin lesions, heartbeat irregularities, and a some deaths here and there.

Inside the site, there is no person's name, and only two mail-drop addresses, where the company collects payments for its basic product: a book full of contact numbers of recruiters in research facilities. I've seen an early version of this glorified piece of crap. It's a list of all the phone numbers, old or new, for every type of researcher that ever conducted an experiment or gathered data to develop

(continues on page 33)

Terry's Place continued...

like one, it happens. The beveled point sinks down under the skin about an eighth of an inch, and the vacuum tube is pushed against the other end. I watch the thin jet-stream of my dark personal juices fill the tube, and she pops off the rubber strap, takes the tube away and sets it down, and drops a gauze pad over the spot where I've been penetrated. Then out comes the needle and she presses down on the course white cloth.

"There you go... need a band-aid?" Audrey asks.

"Tough guys don't use band-aids," I reply, and it's all over. Just another bug-bite in the swamp-land of science.

Tomorrow is pay day. \$1,250 for a seven-day stint, with no side effects. Wyeth pays in full upon completion, so you walk out the door with a check in your hand. Stay on your toes, though, because if you spill a big fruit salad in the TV lounge or come late to a blood draw, they'll fine you good. There's also an instruction sheet about how to cash the checks, because they figure (with good reason) that you're one of those guys who actually walks into check-cashing places during life, and knows about other poor-person devices like pre-paid calling cards.

So, fellow lab rat, if you're in Philly, your piss is clean, and you're looking for cash, maybe we'll meet down at Terry's Place!

Mickie went out walking for a couple hours.

In the morning we arrived at 8:00 a.m. A new nurse indicated that the doctors wished to speak to us in an hour or so about why they should continue with their efforts. We went to have breakfast at the hospital cafeteria. I knew and told Mickie we should be prepared for a funeral. She wanted to believe he would get well. Drs. Batshaw and Raper were there when we returned. They told us that Jesse had suffered irreparable brain damage and that his vital organs were all shutting down. They wanted to shut off life support. They left us alone for a few minutes and we collapsed into each other. On their return, I told them that I wanted to bring my family in and have a brief service for Jesse prior to ending his life. Then I told them that they would be doing a complete autopsy to determine why Jesse had died, that this should not have happened. While waiting for my siblings, moments of anger toward the doctors would sweep over me. I would say to myself, "No, they couldn't have seen this." I went so far as to tell Dr. Batshaw that I didn't blame them, that I would never file a lawsuit. Little did I know what they really knew.

Seven of my siblings and their spouses and one of my nieces were present for the brief ceremony for Jesse... more for us at this point. I had all the monitors shut off in his room. Leaning over Jesse, I turned and declared to everyone present that Jesse was a hero. After the chaplain's final prayer, I signaled the doctors. Dr. Shapiro clamped off Jesse's blood flow to the ECMO machine and shut off the ventilator. After the longest minute of my life, Dr. Raper stepped in and I removed my hand from Jesse's chest. After listening with a stethoscope for a moment he said, "Goodbye, Jesse, we'll figure this out." Not a dry eye all around. This kid died about as pure as

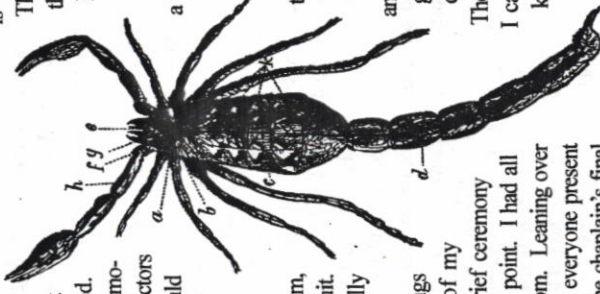
it gets. I was humbled beyond words. My kid had just shown me what it was really all about. I still feel that way.

I supported these doctors for months, believing that their intent was nearly as pure as Jesse's. Even after the media started exposing the flaws in their work I continued to support them. I had discovered that federal oversight was woefully inadequate, that many researchers were not reporting adverse reactions and that the FDA was being influenced into inaction by industry. I decided to attend the RAC meeting in December where all the experts were to discuss my son's death. It wasn't until that three-day meeting that I discovered that there was never any efficacy in humans. I had believed this was working based on my conversations with Mark Batshaw and that is why I defended Penn for so long.

These men could not go in front of their peers at the RAC meeting in Bethesda and say this was working.

After Penn and the FDA made their presentations on Dec. 9, I asked for a lunch meeting with the FDA, NIH and the Penn doctors. After touching on many issues I let them all know that I had not to this point even spoken to a lawyer, but would be in the near future. Too many mistakes had been made and unfortunately, because of our litigious society, it was the only way to correct these problems.

There is so much more to Jesse's story. I can't help but believe that they will kill this with time and money, as they always seem able to do. Who is "they"? They are heartless and soulless industry and their lobbying efforts; they are the politicians more interested in placating industry than in protecting the people, they are doctors so blinded in their quest for recognition that they can't even see the dangers anymore. Let them apply Jesse's intent to their efforts, and then they'll get it right.



PATIENT OR

Nancy M. P. King

I stole that title from the *New York Times*. It's from the headline on an article by Sheryl Gay Stolberg, "Patient or Guinea Pig? Dilemma of Clinical Trials," which I read in the *Times*' on-line version dated January 5, 1999. The article was about a randomized controlled trial of an expensive intervention that the patient-subject profited could not afford off-study; it discussed the pharmaceutical sponsor's refusal to release to subjects interim data collected from them that they believed could help them determine whether the intervention they were receiving was working well enough to make them willing to put up with significant side effects and continue in the trial. In short, it addressed some of the problems that can arise when subjects enter trials to get treatment, while sponsors and investigators enroll subjects to get data. These are important problems, but they don't come up only in large randomized controlled trials like the one in the *Times* story. More and more often, they come up in Phase I studies too. For that reason, there are some things that every good guinea pig, as expert participants in Phase I trials, should know about trials that enroll subjects who are also patients.

Desperately Seeking Subjects

Consider a typical newspaper ad soliciting guinea pigs. In my local papers, the most common ones are from PPD Development, Inc.. They always start off this way: "Earn money while contributing to the future of medicine." They list studies by the maximum potential payment, the demographics of the subject group sought (for example, women between the ages of 18 and 45; nonsmoking men over 50; etc.), and the dates of required study visits and confinements. If you want to know what is being studied, you have to call for more information. Recruitment ads like these are pretty clear and straightforward, emphasizing the exchange of human data for income. But there are a lot of other subject-soliciting ads in my local paper too. They come from academic medical centers and private medical practices, as well as from private

research groups. They usually go something like this: "Do you suffer from X Disease? You are not alone! You may be eligible to participate in a research study of a new treatment. If you qualify, you will receive a free physical exam and free study medication." Payment is rarely offered. This kind of ad also appears in TV and radio spots. Recruitment ads even show up on local TV disguised as news, in which a "medical breakthrough" is described as being studied, and a number to call for further information is flashed on the screen.

The very sickest patients are not usually targeted by advertising, though. Instead, when a patient receives a grim diagnosis, his or her doctor may offer several treatment options, including participation in a study or two, or suggest that the patient might want to go talk to "my colleague Dr. X, about the study she is conducting for patients with your condition." These ads and referrals soliciting subjects who are also patients are often for phase I studies of interventions never before tried in humans—exactly the same kinds of studies in which guinea pigs specialize.

Why Use Patients?

Phase I studies enroll patients with the disease or condition of interest, instead of healthy volunteers, for two reasons. First, the data collected from healthy subjects—even data about safety, which is what Phase I studies are all about—might not apply at all to patients. Yet patients will be the subjects in Phase II and III studies, as well as the ultimate consumers of the intervention if it is promoted to a treatment. For example, suppose that laboratory and animal studies show that the intervention will probably have adverse effects on the livers of patients with the disease to be treated, but will probably have no effect on healthy livers. Data from healthy subjects will not help develop a safety profile of this intervention, or help establish the maximum tolerated dose.

Second, the intervention might pose excessive risks of harm to healthy subjects. For example, suppose that laboratory and animal studies show

list. More importantly, one does not get the feeling that there's something you'd want to know that he's keeping to himself. The screening and the informed consent process are done smoothly, so that the volunteer's time is not wasted, and everyone has clear expectations. You get your own copy of the consent form (to keep) upon signing it. You know whether you'll be an alternate or have a regular slot, given that your labs come back OK. For these reasons, the unit is called "Terry's Place" at least as often as it's called Wyeth in conversations between experienced guinea pigs. Also, the nurses are all nice people, and they know their stuff.

It has generally been difficult getting Terry on the telephone over the years, and guys would get discouraged or think he was sticking to an "A-list" and they weren't on it. The problem has been solved since the company took on a

very sharp lady as his assistant.

Another thing that has improved since last time is the general temperament of the guys who are let into the studies.

The 25 men with whom I've spent the past week are

a good, civilized group, and although one kid wanders on the border between extreme immaturity and insanity, no one is rowdy or obnoxious to other volunteers or to the staff. There are even a few foreigners (from Colombia and the Camaroon) who lend a European hostel touch to those long conversations. This is totally different from some places, where almost anyone is accepted, and studies take on a certain dicey, correctional aspect. Wyeth still gets its share of creeps, but

the radar has been tightened up, and this is good. The moment when bio-sluts like myself actually deliver the precious data, when we have our most tender moment on the job, and when our bodies are invaded by science, is almost always when we report for a blood draw. For some reason, Wyeth never uses catheters, so every draw is a straight needle-stick into that knotty old vein. This is why the lab technicians are important. When they know their craft, all is well, but if they don't, then word of their clumsiness sweeps across the unit like a wind of terror.

I've had 32 needle-sticks this week, and only one of them had to be tried again. The weekend-staffer went too far to the side of the vein, and started to push the needle farther in. A second later, as the underlying arm-meat offered me pain, I stated, bluntly and

firmly, "That's too deep." She withdrew, tried the other arm, and it went fine.

All the other sticks this week were as smooth as silk. For example, here's Audrey, a passionate

lover of animals, who has staffed the lab at Wyeth for years. Audrey never misses. After she stretches the tourniquet into place, her gloved forefinger taps the antecubital area, where the scar of our profession waits to be thickened again. "Open and close your fist," she says. She finds the blood vessel, deftly removes the cap from the needle, and lays it down, like a big mosquito landing, on my arm. With two quick movements that seem



Eddy Gourmet, Audrey's pampered pooch "She's a good jumper", says the proud owner.

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Check Out..

"TERRY'S

A GPZ Report Card

by Bob Helms (Summer, 2000)

Wyeth-Ayerst Pharmaceuticals
1300 Wolf Street, South Philadelphia

Located just behind the Methodist Hospital and convenient to the Broad Street subway line, Wyeth's research unit is in a separate, one-story building. It contains an office suite and reception area, a sunny dining room (where I'm writing this), which also serves as a place to hang around waiting for a dose or a blood draw. Attached to the dining room are the blood & urine lab, a small kitchen, and an entrance into the back. Going farther, you'll pass two TV lounges, the nurse's station, and then pass into a long corridor with 14 little bedrooms. There's a very small yard in the back, where you'll be allowed to sit and breathe the fresh air, but you can't see anything from there except some brick walls.

Each room has three beds, a desk, and a bathroom with a shower, but no telephone. In the unit there are four TV sets: one for games, two mainly for videos, and the last is in the dining room, just so that every last inch of air space will almost always be polluted with idiotic noise. If you have a problem with this, just get used to the tiny bedroom.

Other distractions available in the place are a laundry room for longer studies, quite a few books (of random quality), a few magazines, three different daily papers, and some board games, including chess.

The building is in good physical condition. Everything works and is kept clean. It also has large windows in about as many places as it possibly could, so that sunlight and the view of a 50-foot stretch of street or parking lot can relieve the lab rat of that inevitable claustrophobia, at least a little.

PLACE"

The food is a shoe-size better than it was a few years back, but don't come here expecting anything beyond plain, institutional fare. The meals come over from the hospital in carts, and then the staff heats them up, adds drinks and side dishes, and hands them out. One particular feature here is that they'll have you fill out a menu sheet every day, which gives you the choice of various boring meals with small (but adequate) servings. I wish they would forget the choices and just add to the volume, but I believe the meals are this way so you'll neither gain nor lose weight, and that the management thinks the choices improve the quality of life. On the other hand, they might be stuck with the meal plan of the hospital. All I know for sure is that when I get out tomorrow, I'll be stuffing my face in a very serious way.

Parking is free in the Hospital's lot, if you make sure the Wyeth staff stamps the back of your ticket. On the other hand, there are not enough telephones, or even close to enough. Two phones are shared by all forty subjects on the typical day at Wyeth, and both of them are in the same room as a TV set, so very often, you just can't win. I don't know where I get the idea that ten or fifteen phones would be more appropriate. Being born in the "first world," perhaps? Knowing that it wouldn't cost an awful lot? Who knows?

Recruiting is handled by a popular man named Terry Powell. He's been there a long time, and he demonstrates the benefit of having a single, focused recruiter rather than having us talk to whichever nurse picks up the phone, as is the case in some places. Terry is real but professional, and he'll expect the same from you if you call him up looking for a gig.

Terry is respected by the guinea pig population because he maintains a mutual trust. If you're reliable, you can come back again, but if you jerk him around, he'll cut you from the

GUINEA PIG

that the intervention is highly toxic to everybody's livers, healthy or otherwise. It may be very important to develop this intervention anyway, if the good it can do seems potentially great enough; or it may be important to gather data to see if there are ways to reduce the potential for liver toxicity, for example through careful monitoring or dose adjustments. But it may not be fair to ask healthy subjects to take that great a risk. So for phase I trials of interventions like the ones just described, patients are usually enrolled as subjects instead.

Ethically, you can't just pay guinea pigs more to take greater risks in research. Study payment is supposed to compensate people for their time and trouble, not for the risks they take, because money can't make up for an injury, but a lot of money might unduly induce some people to take a risk they would otherwise avoid. That doesn't mean it's morally wrong to want or need the money; it means it's morally wrong to offer too much, because it could exploit people and reduce the incentive to make research participation safer.

But as the ads demonstrate, trial participation is "sold" very differently to healthy people and to patients. Investigators generally tell healthy people something like this: "Sure, research is a risky business. But it is our job to protect you as much as possible, and your participation is likely to help us develop something we think will turn into a helpful treatment in the future."

They generally tell patients something more like: "Yes, this intervention could be dangerous. But we wouldn't ask you to take that risk if we didn't think it could help people with your disease."

In many cases, especially when the intervention

is very dangerous (for example, high-dose chemotherapy), only patients for whom nothing else has worked are asked to participate. The reason for this is so that they are not prevented, by their participation in research on something unknown, from getting any treatment that it is known could help. But the effect is that both patients and their doctors could see an untried and unknown research intervention as the "only hope"—and believe that the risk of harm is worth taking because it might help. That belief is almost never justified in phase I trials. Thus, it might not be fair to ask patient-subjects to take very great risks either.

Why Not Treat Subjects?

The differences in how healthy people and patients are viewed, approached, and talked to about becoming subjects both reflect and create what is known as the "therapeutic misconception"—that is, mistaking research for treatment. I say "both" reflect and create" because I think that just about everybody involved in research with patient-subjects can suffer from the therapeutic misconception and perpetuate it too. This includes patients, families, and advocates; doctors and other health professionals; investigators and other study staff, such as study nurses and site coordinators; members of IRBs, the FDA, and academics in bioethics too.

The essence of the therapeutic misconception in phase I studies is simple. Healthy volunteers can't possibly benefit from getting a study intervention

because they don't have the disease it is hoped the intervention will ultimately treat. Therefore, guinea pigs either are altruists or are in for the *quid pro quo* "I'll advance science in exchange for payment"

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"Research participation can seem desirable because [...] it perpetuates hope by offering a chance to try something that could in theory work better, or just a chance to try something rather than nothing."

—or a little of both. Patients, however, are a different story. Even if an intervention has never been used in a single human before, in order to make the case that research in humans should go forward, investigators need a plausible argument—and laboratory and animal evidence—supporting the proposition that it could ultimately be an effective treatment. Since the patients who will be subjects have the right disease, in theory they could get lucky and it could work for them. Ergo, they aren't altruists, and they don't need to be paid, either. They are enrolling in order to get an early shot at a cutting edge new treatment.

But the argument that in theory, a patient-subject could get lucky and benefit from the intervention in a phase I trial is seriously flawed in several ways. First, the theory is valid only if the drug or whatever is being studied, does actually work.

And very few promising-looking new interventions end up as effective treatments. So the real potential for benefit is extremely low, even when laboratory and animal evidence is strong.

Second, in Phase I trials, what is being tested is safety and toxicity—not efficacy. Any benefit to patient-subjects is beside the point. It isn't being systematically measured, it isn't being addressed in the research design, and it isn't usually going to be available for long, even if it is actually there.

Third, even when investigators genuinely believe they can provide benefit to patient-subjects in phase I trials, their belief has serious limits. On the one hand, they are conducting research, not treating patients. They must enroll a certain number of patient-subjects, so they simply can't be looking only to the benefit of individual patients as they would if they were giving treatment. They have to go out and find a certain number of patient-subjects to try to benefit in order to try to benefit any. But on the other hand, because they are conducting research, they need patient-subjects who meet all the

inclusion criteria and don't meet any of the exclusion criteria. So they can only try to benefit those patient-subjects who can give them good data.

Thus, theoretical benefit to patient-subjects from participation in Phase I studies is extremely low. Practical reality makes it even lower.

Things to Know and Things to Ask

Every guinea pig has rights and interests. And good investigators are willing, even eager, to protect and promote them. This is just as true when the guinea pigs are also patients. Experienced guinea pigs can be valuable instructors and advisors to friends and family members who are patients considering participating in research about their disease. Ideally, they could teach physician-investigators a few things, too. Here's my list of things to remember, look for, and discuss.

(1) There are three principal duties of investigators to research subjects, whether or not the subjects are also patients:

- * Make sure involving humans in the research is worth it—that is, the research must address a worthwhile question and must be properly designed and conducted to contribute to scientific knowledge.

- * Minimize the risks of harm to subjects.

- * Seek and obtain the subject's informed consent.

(2) Patients who become research subjects are not the investigator's patients. They are still research subjects. The investigator does not have a therapeutic duty to benefit them. But the investigator's duty to minimize harms to them means two important things:

- * Every patient-subject is still somebody's patient. Their personal physicians should know about the research, should advise them about how participating might affect treatment options (would it delay starting standard treatment? would it prohibit taking medication that has been helpful? etc.), and should monitor them as closely as necessary during the research.

"The real potential for benefit is extremely low, even when laboratory and animal evidence is strong."

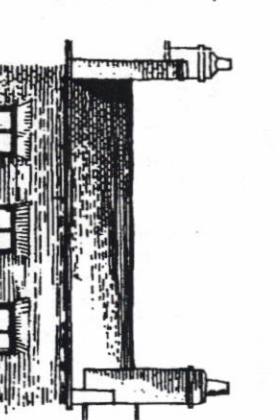
The Skeletons in Ben Franklin's Closet

By Alison Lewis

Benjamin Franklin (1706-1790) is best known for being one of the founding fathers of the United States, acting as elder statesman at the Constitutional Convention and helping to draft the Declaration of Independence.

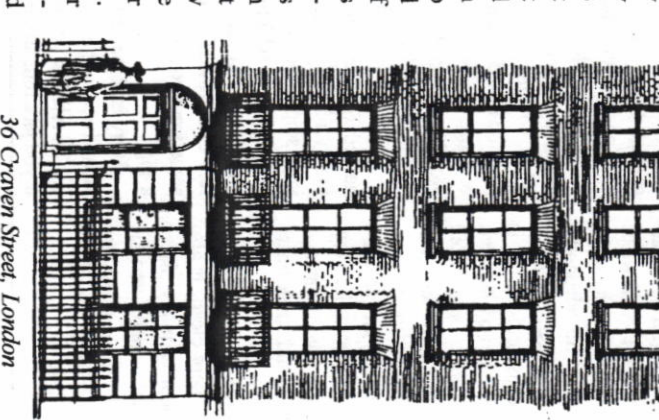
Because of the historic significance of this house they lived in, located at No. 36 Craven Street, a group of American and English Franklino-philes have purchased the house and have begun renovating it. A grisly discovery was made in 1998 when workmen began digging in the basement.

Bones. Lots of bones. Lots and lots of bones, all dating from the time period of Franklin's stay in the house. Could our beloved founding father have been involved with some sort of unsavory crime, like mass murder?



Researchers suspect that the bones are actually the products of an anatomy school that met for a

where the "A Penny Saved" is a Penny Earned" stuff comes from. But what a lot of Americans don't know is that good old Ben actually lived in London from 1757 to 1775, when he served as a representative of the American colonies to the British Parliament. While he was there, he lived with Mrs. Margaret Stevenson, a widow who rented him the upper rooms of her house. Mrs. Stevenson and her daughter, Polly, became like a second



cont'd on p. 30

PATIENT OR GUINEA PIG? cont'd...

patients need and deserve caring, support, and protection, as well as effective treatment when it is available. Of course, a surprising amount of standard medical treatment doesn't work very well, or hasn't been proven effective, or both. Research participation can seem desirable because it offers patient-subjects access

to more care and attention than uninsured or underinsured patients can afford; or because it perpetuates hope by offering a chance to try something that could in theory work better, or just a chance to try something rather than nothing.

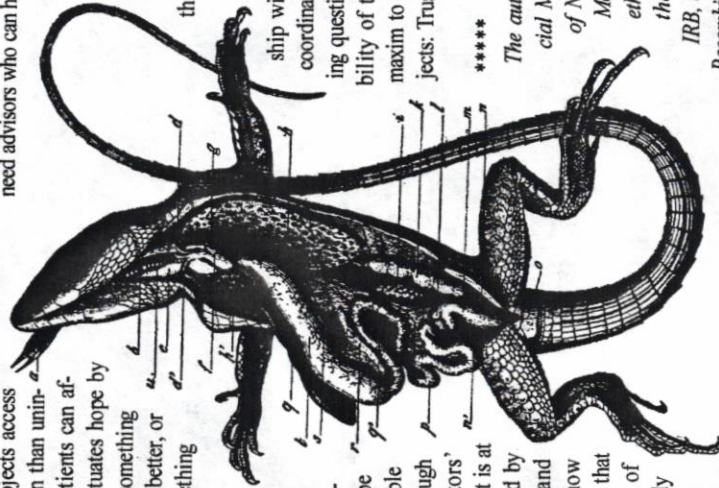
Patients who might become subjects in phase I trials deserve to be reminded that caring, support, protection, and hope can and should be available "off-study" as well as through research; that investigators' ability to provide treatment is at best severely compromised by research requirements and constraints, no matter how good their intentions; and that phase I subjects' chance of benefiting from the study intervention is very small, if it exists at all. Important social justice questions about access to health care, payment for care, and the lack of social support (including palliative care) for sick people are all raised by the growth in the

clinical research industry, but they can't be answered by research participation, any more than the Dutch boy's finger could rebuild the dike.

There has got to be more discussion of these larger social issues, but in the meantime, patient-subjects deserve informed decision-making. They need to be given good information, and they need advisors who can help them ask questions and evaluate the answers. Ex-

perienced guinea pigs could be great advisors for friends, family members, and other patients in this position. Guinea pigs know the value of engaging in an active relationship with investigators and study coordinators, the importance of asking questions, and even the applicability of this all-purpose political maxim to research with human subjects: Trust, but verify.

The author is a professor of Social Medicine at the University of North Carolina School of Medicine. She is a research ethics scholar, a member of the School of Medicine's IRB, and also a member of the Recombinant DNA Advisory Committee of NIH. Her views are not attributable to any of these bodies, but are entirely her own.



"Sorry children. Papa has sold you all off for medical experiments."

-Monty Python, The Meaning of Life

* There should be an independent clinical monitor on the study, who will ensure that participation is not harmful and who can stop the participation of subjects who are at great risk.

(3) The consent form and process should specifically discuss the potential for patient-subjects to benefit from getting the intervention being studied. That means one of two things:

* If benefit is impossible or highly unlikely, the consent form should clearly say so. This is almost certainly true in most phase I studies. Something like this should be said: "The purpose of this study is to test the safety of the study drug. We do not expect you to experience any benefit from receiving it, but we hope that your participation will provide information that can help other patients in the future."

* If benefit is genuinely and reasonably possible (which might sometimes be true in early trials if there is enough evidence from laboratory and animal studies, from similar studies, or even from very small prior studies in humans), it must be very thoroughly described, so that its limits are clear. For example: "This drug has not been tested in humans, and the purpose of this study is to test its safety, so we do not know whether it can be of any benefit. In animal studies, 20% of the animals had a temporary and partial response to the highest doses of the drug. Because this is a dose-escalation study, only 2 or 3 subjects will receive the highest dose. We do not know if any subjects will have a response, or how great that response might be, or how long it might last."

If all that sounds pretty complicated, think about how consent forms already describe the risks of harm to subjects. Every consent form describes the nature, magnitude (size and duration), and likelihood of the risks of harm, and in phase I studies all of that information comes from laboratory and animal research. So experienced guinea pigs should recognize that something similar can and should be done for benefits—including that there aren't any, whenever that is true. This is really important for patient-subjects to hear, but it often isn't done. Instead, the consent form often says nothing more than "You may or may not benefit from participat-

ing, but your participation will help others" -- even in studies where benefit is impossible.

(4) The consent form should also explain several other aspects of study design that can have important implications for harms and benefits to patient-subjects, including:

* use of a dose-escalation design, in which potential benefits and risks of harm may change depending on which cohort the subject is in, any restrictions on treatments that subjects can get while they are in the study, alternatives to study participation, which include not only standard treatments known to be effective but also partially effective or symptomatic treatments, and palliative and supportive care when applicable, and

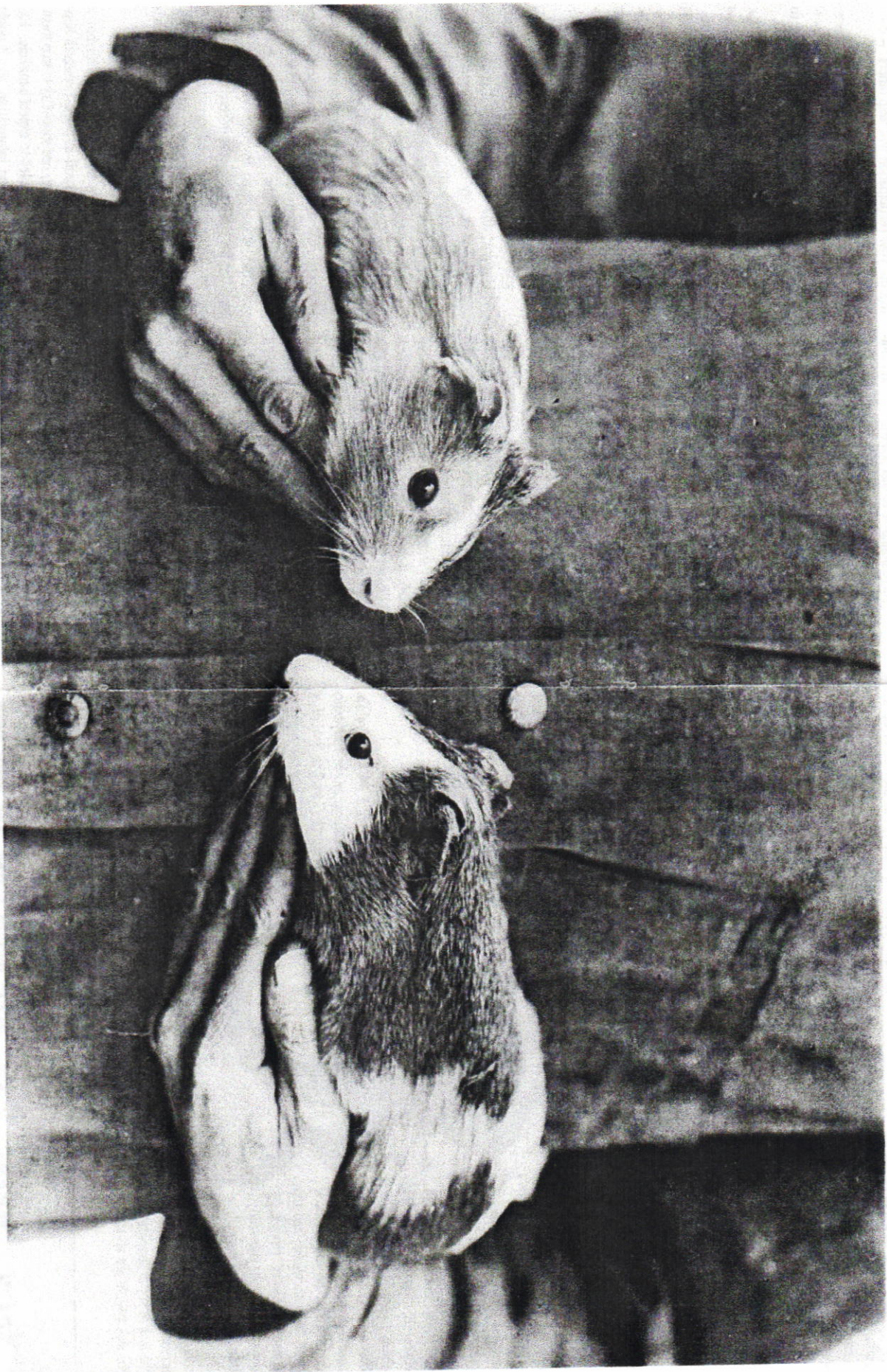
* the differences between the purposes and goals of the line of research of which this study is a part and the purposes and goals of this study. It is very easy to inadvertently "oversell" research participation by describing the investigators' ultimate hopes for the success of the intervention, and not also discussing the more limited expectations from a Phase I trial.

(5) Subjects should be called subjects, not patients, and the research intervention should not be called treatment. Using "patient" and "treatment" is very common, and even understandable, but it also increases the therapeutic misconception for both investigators and subjects. Investigators do care about and care for patient-subjects in research, but they can prove that by being good investigators, not by pretending to be the subjects' doctors. Nobody should feel that they have to use misleading terminology to demonstrate caring and establish trust.

Hope, Care, and Research

Finally, there's nothing wrong with hope. Patient-subjects can enroll in phase I research hoping for a miracle, and no one should try to stop them. They just shouldn't be led to expect a miracle. Expectations are based on information, and it ought to be good information. This is just as true for medical treatment as it is for research participation, but it is more important in research, because the overriding goal of research is to benefit science, society, and future patients—not current subjects. Whether their conditions are serious or not, all

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"I was deputy chief of my department [at the Mayak plutonium factory, Plant 25] and one night my chief gave me a task overseeing the work of some soldiers. When the soldiers had received the maximum allowable dosage [of radiation], I stopped their work. The next morning my chief was angry and he explained to me that the maximum dose applied only to plant personnel. Soldiers could receive more, and prisoners much more – because they would leave Mayak after they had finished serving their time, and nowhere would the doses they received be recorded."

Inna Razmahova, recalling her work of the 1950's in the Soviet Union, in Vladislav Lavin, "Mayak's Walking Wounded," in *Bulletin of the Atomic Scientists*, Sept/Oct 1999

PHOTO:
Geneticist Sewall Wright holding a guinea pig in each hand, c. 1920.
(Library of the American Philosophical Society)